Federation of American Hospitals®

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The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1716-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals (Vol. 84, No. 86), May 3, 2019

Dear Administrator Verma,

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the referenced Notice of Proposed Rulemaking on the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals.

EXECUTIVE SUMMARY

Wage Index

The FAH applauds CMS's recognition of the negative feedback loop the wage index creates for low wage hospitals and strongly supports CMS addressing this critical problem that disproportionately impacts rural hospitals through an increase to the wage index values of low wage index hospitals. The FAH, however, prefers that this policy be implemented in a non-budget neutral manner and believes that CMS has the authority to increase the wage index values

of low wage index hospitals without adversely impacting other hospitals by adopting a non-budget neutral adjustment under subsection (d)(5)(I).

Rural hospitals play a critical role in ensuring access to care for the approximately 60 million Americans that live in rural areas across the United States. Dependence on rural hospitals is particularly acute for Medicare beneficiaries—close to one-quarter of Medicare beneficiaries live in rural areas and depend on rural hospitals for care. Because Medicare beneficiaries disproportionately rely on rural providers to access care, Medicare reimbursement tends to have a greater influence on rural hospitals' revenue as compared to non-rural hospitals. The wage index, however, has aggravated rather than ameliorated financial problems for many rural hospitals.

The FAH also supports CMS's proposal to adopt a transition wage index to help mitigate significant decreases in the FY 2020 wage index values of hospitals. However, while the proposed 5-percent cap on any decrease in a hospital's wage index as compared to FY 2019 would appropriately limit what would otherwise be significant downward adjustments for certain hospitals in FY 2020, the FAH recommends a longer transition to support hospitals that may continue to experience a significant decrease.

The FAH strongly opposes the exclusion of accurate and verifiable wage data for certain general, acute care hospitals based on CMS's belief that the data does not reflect the prevailing market conditions. In the Proposed Rule, however, the Secretary identified and excluded eight (now seven) hospitals (the "Seven Hospitals") that are all part of the same health system. Yet the Secretary does not identify any concerns with the accuracy or verifiability of these Seven Hospitals' wage index data.

The rationale provided is not appropriate, and the exclusion of the Seven Hospitals' data without any definable standards creates uncertainty for all hospitals whose salary negotiations could later be second guessed for "reasonableness." Further, while the exclusions will harm IPPS hospitals and beneficiary access to inpatient care, they will also significantly harm inpatient psychiatric facilities, inpatient rehabilitation facilities, and other provider types whose payments are impacted by the wage index.

Medicare Disproportionate Share Hospital (DSH) Payments

The FAH and its members commend CMS for its efforts over the past several years to: (1) better define the costs of uncompensated care, in particular by including the cost of uninsured discounts into the definition of charity care for Worksheet S-10 ("WS S-10") purposes to be consistent with ACA section 3133's mandate; (2) better define the terms of its instructions to providers for the preparation of WS S-10 so that costs are more accurately and consistently reported by hospitals; (3) allow providers to amend their WS S-10s to comply with CMS's revised instructions; and (4) develop, engage in, and improve an audit process aimed at more accurately allocating and disbursing the uncompensated care fund to providers. Given the relative weights Factor 3 assigns to hospitals, the FAH appreciates CMS's recent efforts to rigorously audit hospitals' reported data to make sure hospitals are reporting costs consistently.

The FAH strongly supports CMS's proposal to use audited FY 2015 cost report data in the computation of Factor 3 and the allocation of uncompensated care DSH. On balance, the FAH believes that the extensive corrective actions taken on the FY 2015 WS S-10 data through public comment, additional scrutiny, and CMS audit and review, far outweigh the potential benefit from improved cost reporting instructions in place beginning with FY 2017 cost reports.

New Technology Payment/CAR T Cell Therapy

The FAH strongly supports CMS's proposal to increasing the maximum new technology add-on payment in response to stakeholder concerns that the current new technology add-on payments are inadequate, particularly regarding very high-cost new technologies like the CAR T-cell drug products. Under CMS's proposal, the new technology add-on payment amount would be the lesser of 65 percent of the costs of the new medical service or technology or 65 percent of the amount by which the costs of the case exceed the standard DRG payment. The FAH, however, believes this amount will still be inadequate as a general matter and that 80 percent would more accurately reflect costs.

Moreover, the FAH supports the adoption of an alternative new technology add-on payment for very high-cost new technology, like CAR T-cell drug products, where the cost of the technology substantially exceeds the applicable MS–DRG payment. This can be done, for example, under CMS's exceptions and adjustments authority or through a demonstration program after FY 2020.

Regarding CAR T-cell therapies for FY 2020, the FAH supports CMS's proposal to continue new technology add-on payments for KYMRIAH® and YESCARTA®. In order to mitigate risk, maximize price-based competition between existing and emerging CAR T-cell therapy manufacturers, and improve access to care, the FAH recommends that CMS provide for the applicable MS–DRG payment plus a new technology add-on payment that represents the blended average sales price (ASP) for substantially similar CAR T-cell therapies T-cell therapy, starting with KYMRIAH® and YESCARTA®.

The FAH agrees with CMS that it would be premature to consider creation of a new MS–DRG for cases involving CAR T-cell therapy for FY 2020. At present, CMS does not have sufficient, accurate data to create and appropriately weight a new MS–DRG for CAR T-cell therapy. Moreover, the significant costs of CAR T-cell therapy—which are beyond the control of individual hospitals—risk disrupting the IPPS as a whole, including Medicare's MS–DRG payments and inpatient outlier payments, while also creating a barrier to access. Accurate weighting of an MS–DRG for CAR T-cell therapy necessitates establishing a separate cost center, and an interim payment solution will be required as cost reports are submitted with CAR T-cell therapy drug product data in the new cost center.

Long-Term Care Hospitals (LTCHs)

CMS is proposing new regulations to implement the requirement that, for cost reporting periods on or after October 1, 2019, unless at least fifty percent of the LTCH's discharges qualify for payment under the LTCH PPS, all discharges will paid an IPPS comparable amount, subject to a "process for reinstatement."

Whereas the proposal to shift payment to comparable amounts under the IPPS for all discharges in subsequent years is generally consistent with the governing statutory provisions, the proposed mechanics of the application of this requirement, and in particular, the proposed mechanics of the special probationary reinstatement process, raise several issues of concern to FAH, that we recommend CMS address in the final rule. For example, the FAH agrees with CMS's proposal to allow providers a "second chance" to show compliance with the discharge payment percentage requirement, but asks CMS to consider changes that would shorten and simplify the reinstatement process. CMS's proposed implementation of the 50 percent discharge payment percentage requirement would take too many years to resolve an LTCH provider's

reimbursement both prospectively and retrospectively, and further unduly "punishes" providers on a retroactive basis.

In addition, the FAH strongly disagrees with CMS's proposal to apply an additional 5.1% BNA for site neutral cases that qualify as high-cost outliers. As the FAH explained in previous years' comments, this BNA is duplicative and unwarranted because CMS has already applied budget neutrality adjustments to reduce the operating and capital portions of the IPPS standard Federal payment rate by the same 5.1%, before using that rate to determine the IPPS comparable per diem amount for site neutral payment cases.

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II.D. FY 2020 MS–DRG Documentation and Coding Adjustment

CMS proposes making a permanent 0.5 percentage point positive adjustment to the standardized amount for FY 2020, following the 0.4588 percentage point adjustment in FY 2018 and its 0.5 percentage point adjustment in FY 2019, stating that these adjustments are consistent with section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), which delays restoration of the one-time negative recoupment adjustments implemented under section 631 of the American Taxpayer Relief Act of 2012 ("ATRA"). The FAH continues to maintain, however, that CMS misinterpreted the relevant statutory authority, which explicitly assumes that the ATRA section 631 recoupment would result in an estimated 3.2 percent adjustment in FY 2017. Instead, CMS should have made an additional 0.7 percent positive adjustment to the standardized amount in FY 2018, and the FAH believes that the excess 0.7 percent ATRA adjustment has been improperly continued in FY 2018 and FY 2019. Regardless of the correct interpretation of section 414 of MACRA, the FAH urges CMS—as it has previously—to exercise its discretion under 42 U.S.C. § 1395ww(d)(5)(I) and apply a positive adjustment of 0.7 percentage points in addition to the 0.5 percentage point adjustment proposed.

II. F. Proposed Changes to Specific MS-DRG Classifications

For this proposed rule, CMS's MS-DRG analysis is based on ICD-10-CM claims data from the September 2018 update of the FY 2018 MedPAR file, i.e., discharges/hospital bills occurring through September 30, 2018. Based on the review of the rule, the FAH agrees overall with the proposed changes recommended for MS-DRG and/or ICD-10 code classification changes for FY 2020 except for the items discussed below.

II.F.2.a. Pre-MDC – Peripheral ECMO

The FAH strongly agrees with the CMS proposal to move the two current ECMO peripheral codes (5A1522G and 5A1522H) to the same MS-DRG as the predecessor open (Central) ECMO code for FY 2020. This proposal includes maintaining the designation of the peripheral ECMO procedures as a Non O.R. designation affecting the assignment for Pre-MDC MS-DRG 003

The FAH notes that there are new ICD-10-PCS codes that were being considered as per the March 2019 Coordination and Maintenance Committee meeting that were published on 5/31/19, after the release of this Proposed Rule. If CMS approves these additional ECMO codes for October 1, 2019 implementation**,** the FAH requests that these new codes also follow

the same logic change for the peripheral codes noted above, resulting in MS-DRG 003 for all of the procedure codes associated with ECMO. These new codes include the following:

- 5A1522F - Extracorporeal Oxygenation, Membrane, Central Extracorporeal Oxygenation, Membrane, Central
- 5A1522G - Extracorporeal Oxygenation, Perph VA ECMO Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial
- 5A1522H - Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous
- 5A15A2F - Extracorporeal Oxygenation, Membrane, Central, Intraop Extracorporeal Oxygenation, Membrane, Central, Intraoperative
- 5A15A2G - Extracorporeal Oxygenation, Perph VA ECMO, Intraop Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial, Intraoperative
- 5A15A2H - Extracorporeal Oxygenation, Perph VV ECMO, Intraop Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous, Intraoperative

The FAH also calls attention to Tables 7a and 7b within this Proposed Rule. These tables show a decline of MS-DRG 003 when comparing V36 and V37 (15,749 vs 15,164). With the current proposal, we would expect to see a shift in cases to MS-DRG 003 from MS-DRGs 207, 291, 296, and 870 for the peripheral ECMO. Therefore, the FAH requests that CMS revisit these Tables 7a and 7b to provide insight and clarification concerning a potential issue with the surgical hierarchy given that the ECMO codes are not recognized O.R. procedures and V36 volumes are higher than V37 based on the data within these tables.

II-F-6a – MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Knee Procedures with Principal Diagnosis of Infection

The FAH agrees with the proposed addition of ICD-10-CM diagnosis code M00.9, Pyogenic arthritis, unspecified, to the list of principal diagnoses for MS-DRGs 485, 486, and 487 (Knee Procedure with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively).

However, the FAH disagrees with CMS's proposal not to add code A54.42, Gonococcal arthritis, to these MS-DRGs. Neither code M00.9 nor code A54.42 specifically includes the knee in the code title. However, both codes apply to the conditions described in the code titles when they occur in any joint, including the knee. In addition, the DRG logic requires a principal diagnosis code in combination with an ICD-10-PCS code for a knee procedure.

Since code A54.42 is the appropriate code for gonococcal arthritis of the knee (regardless of whether there are specific Index entries for this anatomic site), we believe it should be added to MS-DRGs 485-487 along with code M00.9. As noted above, the ICD-10-PCS code will identify the knee as the anatomic site.

II-F-10 – MDC 22 (Burns): Skin Graft to Perineum for Burn

The FAH disagrees with CMS's proposal not to add seven ICD-10-PCS codes describing skin graft to the perineum to MS-DRG 927 (Extensive Burns or Full Thickness Burns with MV >96 Hours with Skin Graft) and MS-DRGs 928 and 929 (Full Thickness Burn with Skin Graft or

Inhalation Injury with CC/MCC and without CC/MCC, respectively). When principal diagnosis codes T21.37XA, Third degree burn of (female) perineum, and T21.36XA, Third degree burn of the (male) perineum, are assigned in combination with one of the ICD-10-PCS codes for skin graft to the perineum, cases group to non-surgical MS-DRG 934, Full Thickness Burn without Skin Graft or Inhalation Injury. When surgical placement of skin grafts for burns is performed, the cases should group to surgical DRGs with skin grafts. Therefore, the FAH requests that the seven ICD-10-PCS codes describing skin graft to the perineum be added to MS-DRGs 927-929.

II.F.12 - Review of Procedure Codes in MS-DRGs 981 through 983 and 987 through 989

The FAH agrees with the proposals as outlined in F.12 section with the exception of the following:

II-F-12a – Adding Procedure Codes and Diagnosis Codes Currently Grouping to MS-DRGs 981 Through 983 or MS-DRGs 987 Through 989:

II-F-12a(3) - Bone Excision with Pressure Ulcers – The FAH disagrees with CMS's proposal to add the ICD-10-PCS procedure codes describing excision of the sacrum, pelvic bones, and coccyx to MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

Under this proposal, cases reporting a principal diagnosis in MDC 9 (such as pressure ulcers) with a procedure describing excision of the sacrum, pelvic bones, and coccyx would group to MS-DRGs 579, 580, and 581. It does not seem appropriate for procedures performed on bones to be grouped to MS-DRGs for procedures on skin and subcutaneous tissue. Bone excisions are more clinically significant, with higher risk and higher resources than excisions of skin and subcutaneous tissue. We realize that CMS may have selected MDC 9 as it includes all pressure ulcers. However, MDC 9 also includes ICD-10-CM diagnosis code L89.154, Pressure ulcer of sacral region, stage 4, which has the inclusion term "Pressure ulcer with necrosis of soft tissues through to underlying muscle, tendon, or bone, sacral region." The higher severity and resource utilization for these ulcers is determined by the procedure on bone. The FAH therefore recommends CMS consider MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

II-F-12a (5) Kidney Transplantation Procedures - The FAH disagrees with CMS'sproposal to add ICD-10-PCS codes 0TY00Z0 and 0TY10Z0 describing kidney transplantation to MS-DRG 264 (Other Circulatory System O.R. Procedures) in MDC 5. Kidney transplantation is not a circulatory system procedure. Therefore, the FAH believes it is illogical and clinically incongruent to assign resource intensive procedures such as kidney transplantations to the circulatory system when these procedures are performed on the urinary system.

The FAH requests that consideration be given to classifying cases with a principal diagnosis in MDC 5 and a procedure code for kidney transplantation to MS-DRG 652 (Kidney Transplant) in MDC 11, since ICD-10-CM category I13, Hypertensive heart and chronic kidney

disease, captures a combination of circulatory and kidney diseases. If this reclassification is not possible, the FAH requests that these cases remain in MS-DRGs 981-983.

II-F-12c – Proposed Additions for Diagnosis and Procedures - MS-DRGs 981 through 983 or MS-DRGs 987 through 989:

II-F-12c(8) Occlusion of Left Renal Vein – The FAH disag**rees** with CMS's proposal to reassign cases for varicose veins in the pelvic region when reported with an embolization procedure to MS-DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with CC/MCC and without CC/MCC respectively). It is not clear why ICD-10-CM diagnosis code I86.2, pelvic varices, is assigned to MDCs 12 and 13 (Diseases of the Male and Female Reproductive System respectively), as the diagnosis code represents a disease of the circulatory system rather than the reproductive system. The FAH requests that diagnosis code I86.2 be reassigned to MDC 5 (Diseases and Disorders of the Circulatory System). The ICD-10-PCS procedure code describing embolization procedures for the treatment of pelvic varices is already assigned to MDC 5.

II.F.13 - Operating Room (O.R.) and Non-O.R. Issues

CMS noted that a long time has elapsed since the original O.R. and Non-O.R. designations were established. With the incremental changes that have occurred to these procedure code lists and the way inpatient care is delivered during that time, CMS is proposing a multi-year plan to conduct a comprehensive review of designations on procedure codes for O.R. and Non O.R. between initial designation and revision.

CMS is soliciting public comments by November 1, 2019 on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration.

FAH supports CMS's proposal for a multi-year comprehensive review of this topic. The FAH also supports CMS's proposal for an extended time frame to provide comments on this topic. However, FAH is emphatic that CMS provide additional data for each ICD-10-PCS procedure code, and that it do so in a timely manner that allows sufficient time for review by the November 1, 2019 submission date. Otherwise, CMS should provide a new date for comment submission.

The FAH believes that thorough data analysis with provider input is critical. Along those lines, the FAH recommends that CMS convene a technical advisory panel (TEP) comprising industry stakeholders and experts to review methodologies for O.R. determination. The expertise of a TEP is critical in light of industry and technological advancements with procedures and delivery of care to encompass all patient settings.

II-F-13c – Operating Room (O.R.) and Non-O.R. Issues: Non-O.R. Procedures to O.R. Procedures

II-F-13c(2) Endoscopic Insertion of Endobronchial Valves - The FAH disagrees with CMS's proposal not to designate 8 ICD-10-PCS codes describing endoscopic insertion of endobronchial valve as an O.R. procedure until additional analyses can be performed. Patients

undergoing this procedure have higher average costs and longer lengths of stay than other cases in the MS-DRGs to which this procedure is currently assigned. CMS's data supports higher severity level, higher costs, and longer lengths of stay for these patients. For these reasons, the FAH requests that the eight ICD-10-PCS codes describing endoscopic insertion of endobronchial valves be designated as O.R. procedures.

II.F.14 - Proposed Changes to MS-DRG Diagnosis Codes for FY 2020

II.F.14.c.1 – Proposed Changes to Severity Levels The diagnosis codes for which CMS is proposing a change in severity level designation as a result of the analysis described in this proposed rule are shown in Table 6P.1c. CMS described the process for establishing three different levels of CC severity that subdivide the diagnosis codes as MCC, CC, Non-CC. CMS indicated this approach in which each diagnosis code is evaluated to determine the extent to which its presence as a secondary diagnosis increased hospital resources. Readers were referred to FY 2008 for a complete discussion of the approach.

CMS provided Table 14, Impact on Resource, ICD-10-CM Diagnosis Codes with Proposed Severity Level Changes, which contained data describing the impact for each of the 1,492 ICD-10-CM diagnosis codes for which there is a proposed change in severity designation. This CMS table provided the data for the mathematical constructs that were used in the determination of the MCC/CC Severity. CMS provided case counts and a ratio of average costs with three subsets of patients labeled as C1, C2, and C3. CMS provided logic for the use of the file that requires users to look at the majority volume (80% threshold) and ratio within the categories. CMS indicated that values of 1.0 tend to suggest Non-CC, 2.0 or higher suggest CC and 3.0 or higher suggest MCC. In addition to the logic explanation provided in the proposed Rule, CMS noted, "*These mathematical constructs are used as guides in conjunction with judgment of our clinical advisors to classify each secondary diagnosis reviewed as MCC, a CC, or a non-CC.*" CMS utilized the same MedPAR data grouping MS-DRGs with the existing V36 of the Grouper and the proposed V37 of the grouper, which is only available to CMS. The comparison of this data included within Tables 7a and 7b illustrates a shift of cases per MS-DRG.

The FAH analysis of Tables 7a and 7b show that all but 34 MS-DRGs show a shift within the MS-DRG, which demonstrates the sweeping impact of MCC/CC Severity proposals and their impact on all MS-DRGs. Review of the MedPAR data demonstrated that 97% of the MS-DRG shifts were the result of MS-DRG Severity proposals while only 3% were the result of changes within MS-DRG logic.

The FAH recommends that CMS provide a "batch" test grouper be made available in the comment period when there are MS-DRG shifts, especially when the shifts impact the majority of the MS-DRGs. This will allow providers the opportunity to perform a thorough data analysis that would further ensure the submission of more meaningful comments in response to the proposed rule on this topic.

FAH disagrees with and finds confusing the proposal to change the severity on the majority of the diagnoses outlined in this Proposed Rule. The FAH analysis of Table 14 shows 2/3 of the diagnosis codes in which there is a recommended shift meets the CMS mathematical

80% threshold and have C2 and C3 values greater than 2.0 or 3.0 to support the MCC or CC designation.

Accordingly, the FAH respectfully, but strongly, requests that CMS delay the severity level proposals for these 1,492 diagnosis codes as outlined in this Proposed Rule until further evaluation is performed and greater transparency to the logic is made available by CMS. The FAH is especially concerned that the majority of the designations do not appear to follow the math logic outlined in the FY 2020 Proposed Rule and CMS has not disclosed sufficient data to fully evaluate these MCC/CC designations.

Some of the proposed changes seem illogical or inconsistent across codes, suggesting that logic employed to make the severity level determinations may have skewed the data. For example, some conditions assigned a higher severity level designation appear to be clinically less severe and require fewer resources than other conditions with a lower level designation, and vice versa. The following examples from Table 14 illustrate our concern.

- Neoplasms
    - The FAH disagrees with the reassignment of neoplasm codes mostly to Non-CC conditions. The FAH analysis of the table showed that only 149 of the 767 codes that are shifting appear to be supported by the CMS "mathematically construct." The majority of these have higher volumes in upper 80% thresholds and ratios higher than 2.0 or 3.0.

- Diseases of Circulatory System
    - The FAH disagrees with the proposed change in severity level from MCC to CC for the acute myocardial infarction (MI) codes. CMS noted 13 ICD-10-CM codes for I21 and I22 initial and subsequent STEMI codes shift from MCC to CC indicating that the care provided and resources involved are not aligned with those of MCC cases when reported as a secondary diagnosis, per the clinical advisors. Clinically, an MI requires significant resources including diagnostic tests, interventions, and monitoring. And, the majority of these have higher volumes in upper 80% thresholds and ratios higher than 2.0 or 3.0. Accordingly, all MI codes must retain their current MCC status.

    - The FAH disagrees with the proposal that the diagnoses for ventricular fibrillation and cardiac arrest (I46.2, I46.8, I46.9) no longer be designated as MCC. These conditions are acute, life-threatening, and require emergent intervention, as well as requiring additional resources such as diagnostic testing and work-up with treatment of the underlying cause. Cardiac arrest and ventricular fibrillation are already excluded as an MCC if the patient expires. Under CMS's mathematical construct**,** all of these codes meet the volume and ratio criteria to support an MCC designation. FY 2008 data indicated that ventricular fibrillation and cardiac arrest impacted the patient's mortality and deemed patient outcome (expired or alive) were important to consider for the resources used. However, this does not appear to have been considered, or there is an inconsistency with the IPPS logic and clinical advisors. The FAH strongly recommends that the diagnosis codes for

ventricular fibrillation and cardiac arrest as well as ventricular flutter retain their current MCC severity level.

- The FAH disagrees with the proposal to shift Chronic Heart Failure codes I50.22 and I50.32 from CC to Non-CC. Again, under the CMS construct they have 80% of cases in Cnt 2 and Cnt3 and the ratios within C2 are 2.078 and 2.072 respectively, and 3.0233 and 3.0238 in C3. The FAH contends, therefore, retain their current CC designation.

- Respiratory Diseases
  - The FAH disagrees with the proposed change in severity level from MCC to CC for Acute postprocedural respiratory failure (J95.821). For consistency, this code should have the same designated severity level as other acute respiratory failure codes. Acute respiratory failure is a life-threatening organ failure that consumes significant resources. Since code J95.822, Acute and chronic postprocedural respiratory failure and codes in subcategories J96.0-, Acute respiratory failure, J96.2-, Acute and chronic respiratory failure and J96.9-, Respiratory failure, unspecified are designated as MCCs, CMS must retain the current MCC designation for code J95.821.

  - The FAH disagrees with the proposed change in severity level of J45.51, Severe persistent asthma with (acute) exacerbation, from a CC to MCC and recommends CMS not change the severity level of code J45.52, Severe persistent asthma with status asthmaticus. The severity level CC should be retained for both codes.

- Malnutrition conditions
  - The FAH disagrees with the proposed severity level change for E43 (Unspecified severe protein-calorie malnutrition) from MCC to CC and E44.0 (Moderate protein-calorie malnutrition) to shift from CC to MCC. It is illogical that moderate protein calorie malnutrition has a higher severity level than severe protein calorie malnutrition.

  - Both moderate and severe malnutrition codes have 80% of cases within the counts for Cnt2 and Cnt3 and both have ratios greater than 3.0 -- severe has 345,682 cases with a ratio of 3.3797 while moderate has 183,680 cases with a ratio of 3.2746. Therefore, under the CMS construct both conditions clearly warrant their current designation, i.e., Moderate Malnutrition as a CC and Severe Malnutrition as MCC, and the FAH strongly recommends that CMS reverse course and restore their current severity levels.

- Blood Disorders
  - The FAH disagrees with the proposals regarding the following blood disorder codes. CMS's mathematical construct appears to support the current severity level designation for all these conditions, and the resource impact decline is unclear.
    - Proposed shifts from CC to Non-CC include the following anemias: D62 (Acute posthemorrhagic anemia), D61.9 (Aplastic anemia, unspecified),

D59.2 (Drug-induced autoimmune hemolytic anemia), D59.1 (Other autoimmune hemolytic anemias), D59.0 (Drug-induced autoimmune hemolytic anemia), D58.8 (Other specified hereditary hemolytic anemias), D58.9 (Hereditary hemolytic anemia, unspecified)

- Proposed shifts from MCC to CC include the following anemias: D61.810 (Antineoplastic chemotherapy induced pancytopenia), D61.811 (Other drug-induced pancytopenia)
- Proposed shifts from MCC to Non-CC includes Sickle Cell Disease and disorders that are in crisis or with other conditions such as acute chest syndrome or splenic sequestration with codes D57.00, D57.01, D57.211, D57.219, D57.411, D57.419, D57.811, D57.812, D57.819

- In addition, R71.0, precipitous drop in hematocrit, is also currently a CC, and no change to its severity is being proposed. For consistency, the FAH recommends that both codes D62 and R71.0 have the same severity level, and that they retain their current severity level.

- Diseases of the Subcutaneous System
  - The FAH disagrees with CMS's proposal to change the severity level of 150 diagnosis codes involving pressure ulcers. Currently all stage 3 and 4 pressure ulcers are MCC while stage 1, 2, unspecified and unstageable are non-CC. As previously noted, our analysis of CMS's Table 14 applying its mathematical construct supports the current designations for all of the pressure ulcers. The proposal would reduce 50 stage 3 and 4 ulcer codes from MCC to CC while increasing 100 of the stage 1 and 2 ulcer codes from Non-CC to CC.

  - The FAH requests that CMS make available for comment its clinical advisory logic as the treatment and resources differ for lower vs higher ulcer codes. CMS clinical advisors noted that the fact the ulcer developed in the first place is more important than the stage of the ulcer in determining the impact on the costs of hospitalization. It appears that there is inconsistency with this clinical logic and IPPS grouper logic. Not all ulcers develop within the hospital stay as some patients have an ulcer present at the time of admission. Currently, IPPS recognizes the Present on Admission (POA) Indicator and Hospital Acquired Conditions (HAC). Within IPPS, the POA Indicator of Yes for a condition designated as HAC will already result in the diagnosis not being considered for the MS-DRG assignment.

  - The FAH disagrees with CMS's proposal to include all pressure ulcers in the existing HAC category instead of the current designation that involves only stage 3 and 4. CMS provided the volume of cases within each ulcer stage; however, there was no differentiation of those with POA of Yes vs POA of No. CMS only notes that these will be added to HAC 04 Pressure Ulcers – Stage III & IV which will change title to only Pressure Ulcers. The clinical treatment of the lower stage ulcers are not as intensive as the higher stages. It is unclear if this inclusion would dilute or create challenges for long term review of this established HAC or the Hospital Acquired Condition (HAC) Reduction Program. The FAH requests

that CMS provide additional charge and data analysis before moving forward with this proposal to add all other pressure ulcer stages to HAC 04.

- Genitourinary Conditions
    - The FAH disagrees with CMS's proposed change in severity levels for eight genitourinary codes, and strongly recommends that their current severity levels be retained.
        - End-stage renal disease (N18.6) should remain an MCC, as it may require dialysis in addition to other resources.
        - The other conditions (acute pyelonephritis, stage 4 and 5 chronic kidney disease, acute cystitis with and without hematuria, acute prostatitis, and abscess of vulva) should remain CCs instead of changing to non-CCs.

    - In addition, while specific sites of urinary tract infection such as kidney or bladder (acute pyelonephritis and acute cystitis) are proposed to change from CC to Non-CC, no change to severity level is being proposed for urinary tract infection, site not specified (N39.0) which is currently designated as a CC. It makes no sense for unspecified UTI to be a CC, but not acute pyelonephritis and cystitis.

- Obstetric Conditions
    - The FAH disagrees with CMS's proposal to shift the severity level on 22 Obstetric codes, with half shifting to more severe levels and half shifting to less severe levels. Of note, conditions shifting to less severe levels are infections, diabetes and second degree perineal lacerations during delivery. The FAH analysis of the CMS data applying its mathematical construct supports their current severity designations in most cases. The volumes on these cases appear low as expected for the Medicare population. MS-DRGs are utilized in other patient populations that include higher level of obstetrics. The FAH questions whether there is sufficient data to consider the diagnosis changes in this area since Medicare data traditionally includes very few obstetrical patients and, in light of that, whether expertise from a panel of industry stakeholders that utilize Obstetrical MS-DRGS should be considered.

Beyond these examples, it is unclear if the data analysis provided by CMS took into consideration the changes that were already in place for FY2019, specifically the changes for principal diagnosis acting as its own MCC or CC. If not, CMS must reconsider its analysis.

FY 2019 was the first year in which the principal diagnosis acting as its own MCC or CC was implemented, which would impact the MS-DRG assignment on data used for the severity analysis and may well underestimate the impact. FY 2019 also added 8 MCCs; deleted 6 MCCs; added 45 CCs; and deleted 8 CCs. Examples of codes that were included in FY 2019 changes which are ALSO included in the FY 2020 proposals are listed below:

- Codes K35.21, K35.32, K35.33 were added as MCC in FY2019 and FY 2020 proposed rule shifts them to Non-CC

- Codes K35.20, K35.30 were added as CC in FY 2019 and the FY 2020 proposed rule shifts them to Non-CC (these didn't have fifth digits in FY2018)
- The following codes are proposed for MS-DRG shift in FY 2020 and were designated as principal diagnosis acting as its own MCC or CC in FY19: This change would not be reflected in FY 2018 data:
    - Proposal to shift from MCC to CC in FY 2020: L89.103, L89.104, L89.113, L89.114, L89.123, L89.124, L89.133, L89.134, L89.143, L89.144, L89.153, L89.154, L89.203, L89.204, L89.213, L89.214, L89.223, L89.224, L89.303, L89.304, L89.313, L89.314, L89.323, L89.324, L89.43, L89.44
    - Proposal to shift from MCC to Non CC in FY 2020: D57.211, D57.411
    - Proposal to shift from CC to Non CC in FY 2020: K50.012, K50.013, K50.014, K50.112, K50.113, K50.114, K50.912, K50.913, K50.914, K51.012, K51.013, K51.014

As detailed above regarding the 1,492 severity level proposed changes**,** the FAH reiterates our strong recommendation that CMS conduct further evaluations and analysis prior to making changes to the to the MCC/CC Severity Levels to the degree and volume proposed. Additional considerations include:

- With the high volume of ICD-10 diagnoses, should evaluation of MCC/CC conditions consider groups of diagnoses, e.g. cardiac arrest has multiple codes with ICD-10 instead of one ICD-9 code. The consideration of "groups of diagnoses" spreads the volume across multiple codes and could dilute the 80% threshold.
- Have the proposed severity level changes been thoroughly vetted to ensure there is consistency with specified and unspecified sites of the same diagnosis? It appears there is a discrepancy with N39.0 unspecified UTI remaining CC and the more specific acute pyelonephritis, acute cystitis, proposed for revision to Non-CC.
- As part of the re-evaluation of diagnosis code MCC/CC Severity designations, the FAH requests that CMS consider the re-evaluation of the MS-DRGs with two tiers, which was not part of the data analysis. This would include the following 67 MS-DRGs pairs that include only MCC and not CC: 001/002, 005/006, 023/024, 054/055, 056/057, 067/068, 073/074, 080/081, 100/101, 102/103, 124/125, 150/151, 152/153, 175/176, 205/206, 222/223, 224/225, 226/227, 228/229, 231/232, 233/234, 235/236, 246/247, 248/249, 250/251, 258/259, 266/267, 268/269, 273/274, 286/287, 302/303, 304/305, 306/307, 319/320, 383/384, 391/392, 459/460, 461/462, 469/470, 533/534, 535/536, 551/552, 553/554, 555/556, 557/558, 562/563, 595/596, 602/603, 604/605, 606/607, 640/641, 689/690, 693/694, 695/696, 725/726, 727/728, 811/812, 862/863, 865/866, 871/872, 896/897, 913/914, 915/916, 917/918, 922/923, 947/948, 969/970

II-F-14 – Proposed Changes to the MS-DRG Diagnosis Codes for FY 2020: External Requests for Changes to Severity Levels

II-F-14d(1) Acute Right Heart Failure – The FAH agrees with the requestor and recommends designating ICD-10-CM diagnosis codes I50.811, Acute right heart failure, and I50.813, Acute on chronic right heart failure, as MCCs. The resources required are similar to acute diastolic and/or systolic heart failure (codes I50.21, I50.31, and I50.41) and acute on chronic diastolic and/or systolic heart failure (codes I50.23, I50.33, and I50.43), which are classified as MCCs as reflected in the CMS provided data.

II-F-14d(3) –Ascites in Alcoholic Liver Disease and Toxic Liver Disease – The FAH agrees with the requestor and recommends that CMS reconsider and move forward with changing the severity level designation for codes K70.11, Alcoholic hepatitis with ascites, K70.31, Alcoholic cirrhosis with ascites, and K71.51, Toxic liver disease with chronic active hepatitis with ascites, from a non-CC to a CC. This change is consistent with the severity level designation of other ascites codes. Both codes R18.0, Malignant ascites, and R18.8, Other ascites, are designated as CCs.

II-F-14d(7) – Obstetric Chapter Codes - While the FAH supports the proposed changes in severity level for 14 ICD-10-CM obstetric diagnosis codes, we believe that appropriate data sets should be utilized for evaluation of severity level designation of obstetric diagnosis codes. We recognize that MedPAR data cannot be used to evaluate requests for changes in severity level designations for obstetric diagnosis codes due to the low volume of obstetric cases in Medicare claims data. However, the FAH does not agree that this evaluation should be based solely on CMS's clinical advisors' judgment.

II.H.4.a-l. Proposed FY 2020 Status of Technologies Approved for FY 2019 Add-On Payments

There were 12 add-on payment categories approved for FY 2019 that were discussed in the FY 2020 proposed rule. The FAH agrees with CMS's proposal for the below 12 add-on payment categories based on rationale provided by CMS for each in which determination to continue or discontinue is based on the anniversary date of entry on the market. Per notation in the proposed rule, CMS only extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry into the U.S. market occurs in the latter half of the fiscal year.

- Difitelio – CMS proposes to discontinue add-on payment for FY 2020
- Stelara – CMS proposes to discontinue add-on payment for FY 2020
- ZINPLAVA – CMS proposes to discontinue add-on payment for FY 2020
- KYMRIAH and YESCARTA – CMS proposes to continue add-on payment for FY 2020
- VYXEOS – CMS proposes to continue add-on payment for FY 2020
- VABOMERE - CMS proposes to continue add-on payment for FY 2020
- remede System - CMS proposes to continue add-on payment for FY 2020

- ZEMDRI - CMS proposes to continue add-on payment for FY 2020
- GIAPREZA - CMS proposes to continue add-on payment for FY 2020
- Cerebral Protection System (Sentinel) - CMS proposes to continue add-on payment for FY 2020
- AQUABEAM - CMS proposes to continue add-on payment for FY 2020
- AndexXa - CMS proposes to continue add-on payment for FY 2020

remede System - According to the Proposed Rule, cases involving the use of the remedē® System that are eligible for new technology add-on payments are identified by ICD–10–PCS procedures codes 0JH60DZ, Insertion of multiple array stimulator generator, subcutaneous tissue and fascia, chest, open approach, and 05H33MZ, Insertion of neurostimulator lead, right innominate vein, percutaneous approach, in combination with procedure code 05H03MZ, Insertion of neurostimulator lead into azygos vein, neurostimulator lead, percutaneous approach, or 05H43MZ, Insertion of neurostimulator lead into left innominate vein, percutaneous approach. The FAH notes that the descriptor of code 05H03MZ is incorrectly stated in the Proposed Rule as involving the right innominate vein, whereas the correct body part for this code is the azygos vein.

Also, the codes listed for the remedē® System in the Proposed Rule do not match the advice that was published in the Fourth Quarter 2016 issue of Coding Clinic for ICD-10-CM/PCS regarding insertion of a phrenic neurostimulator. Coding Clinic advised assigning code 0JH60MZ for the insertion of the stimulator generator into the chest subcutaneous tissue and fascia and code 05H032Z for the insertion of monitoring device into the azygos vein, plus the appropriate code for insertion of neurostimulator lead into either the left or right innominate vein. The device values for both the code for the stimulator generator and the code for the insertion of the lead in the azygos vein in the Coding Clinic advice were different than the ones indicated by CMS in the Proposed Rule. According to Coding Clinic, for coding purposes, the sensing lead is designated as a monitoring device to differentiate between the sensing lead that monitors the respiratory activity and the electrode that delivers the electrical stimulation.

The FAH requests that CMS revisit this topic and revise as applicable the stated codes to identify placement of the remedē® System to be consistent with the advice published in Coding Clinic for ICD-10-CM/PCS.

II.H.9. Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment

The FAH strongly supports CMS's proposal to increasing the maximum new technology add-on payment in response to stakeholder concerns that the current new technology add-on payments are inadequate, particularly with regard to very high-cost new technologies like the CAR T-cell drug products. Under CMS's proposal, the new technology add-on payment amount would be the lesser of 65 percent of the costs of the new medical service or technology or 65 percent of the amount by which the costs of the case exceed the standard DRG payment. The FAH, however, believes this amount will still be inadequate as a general matter and that 80 percent would more accurately reflect costs. Moreover, the FAH supports the adoption of an alternative new technology add-on payment for very high-cost new technology, like CAR T-cell

drug products, where the cost of the technology substantially exceeds the applicable MS–DRG payment.

Under 42 U.S.C. § 1395ww(d)(5)(K), the new technology add-on payments must be set at "an amount that adequately reflects the estimated average cost of such service or technology." In most cases, an add-on payment that reflects the lesser of 80 percent of the costs of the new medical service or technology or 80 percent of the amount by which the costs of the case exceed the standard DRG payment would better approximate the average cost of the new technology. This higher amount would still address CMS's concern that an add-on payment at 100 percent of the costs of the technology would eliminate the provider's incentive to weight the costs of new technology in making clinical decisions while reducing the risk that Medicare beneficiaries will be unable to access new technology because the add-on payments fail to adequately capture the costs of the technology.

Even with this much-needed adjustment, however, the FAH believes that the new technology add-on payment would continue to be inadequate for certain very high-cost technologies where the cost of the technology exceeds the MS–DRG amount several times over. At present, the two key CAR T-cell therapy drug products (KYMRIAH® and YESCARTA®) are prime examples of the need for an alternative new technology add-on payment methodology that can be applied in appropriate cases. As discussed further below, ***the FAH supports applying a new-technology add-on payment equal to the blended average sales price (ASP) for substantially similar CAR T-cell therapies, starting with KYMRIAH® and YESCARTA®.*** This approach would support price-based competition among CAR T-cell therapy manufacturers while avoiding unnecessary variations in payment based on varying hospital charges for CAR T-cell therapy and cost-to-charge ratios (CCRs). Use of a blended ASP would best reflect the "estimated average cost" of this drug product and would address financial considerations that currently limit the availability of this innovative and life-saving therapy to the detriment of Medicare beneficiaries with limited to no treatment alternatives.

Chimeric Antigen Receptor (CAR) T-Cell Therapy: New Technology Add-On Payment and Payment Alternatives (II.E.2.c & II.H.4.d)

The FAH supports CMS's proposal to continue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2020 and appreciates CMS's request for additional comments concerning the use of alternative approaches to establish appropriate payment for CAR T-cell therapies in FY 2020. The FAH agrees with CMS that it would be premature to consider creation of a new MS–DRG for cases involving CAR T-cell therapy for FY 2020. At present, CMS does not have sufficient, accurate data to create and appropriately weight a new MS–DRG for CAR T-cell therapy. Moreover, the significant costs of CAR T-cell therapy—which are beyond the control of individual hospitals—risk disrupting the IPPS as a whole, including Medicare's MS–DRG payments and inpatient outlier payments, while also creating a barrier to access. And, if IPPS reimbursement for CAR T-cell therapy is inadequate, it creates a perverse incentive for care to be provided on an outpatient basis when inpatient care would be more clinically appropriate.

In order to mitigate these risks, maximize price-based competition between existing and emerging CAR T-cell therapy manufacturers, and improve access to care, the FAH recommends that CMS provide for the applicable MS–DRG payment plus a new technology add-on payment that represents the blended average sales price (ASP) for substantially similar CAR T-cell therapies T-cell therapy, starting with KYMRIAH® and YESCARTA®. Applying an ASP-based new technology add-on payment in addition to the MS–DRG -based payment amount will

support price-based competition among CAR T-cell therapy manufacturers (including any new entrants), provide the necessary data for CMS to project Medicare CAR T-cell therapy utilization and costs, roughly harmonize OPPS and IPPS payment for CAR T-cell therapy for FY 2020, and permit stakeholders to seek a legislative solution if needed. In the alternative, CMS could base the new technology add-on payment on the invoice cost of the drug product. This approach would better reflect the costs of the new technology, as compared to payment at a percentage of charges reduced to costs, but it would be administratively burdensome and would not maximize price-based competition to the same extent that a blended ASP-based payment amount would. Alternatively, the new technology add-on payment could reflect 80 percent of the actual costs of a CAR T-cell therapy case, where those costs are based on the invoice price for the drug product and charges reduced to costs for all the non-drug costs of the case. Again, the blended ASP-based approach better achieves CMS' stated policy goals concerning both access and maximizing price-based competition among drug manufacturers.

Payment of an ASP-based amount in addition to the MS-DRG amount is preferable to other alternatives, including the use of a CCR of 1.0 for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3. First, an ASP-based system has the distinct advantage of encouraging price-based competition among CAR T-cell therapy drug manufacturers as long as the ASP is set using the weighted average sales price of substantially similar CAR T-cell therapy drugs. At this time, the two CAR T-cell therapy drugs (KYMRIAH® and YESCARTA®) are substantially similar in terms of their mechanisms and indications, despite having been assigned separate HCPCS codes. Using a blended ASP for substantially similar CAR T-cell therapy drugs (*i.e.*, the weighted average sales price of KYMRIAH® and YESCARTA®) for payment purposes would maximize price-based competition between manufacturers of substantially similar CAR T-cell therapy drugs. Each manufacturer would have a strong incentive to adjust its price to just at or below the blended ASP. Thus, whenever the blended ASP for CAR T-cell therapy drugs declined in a quarterly ASP update, the manufacturer of the higher-priced CAR T-cell therapy drug would likely compete for market share by reducing its CAR T-cell therapy price to or below the blended ASP price. Because each price reduction would prompt a quarterly reduction to the blended ASP, and reductions in the blended ASP would incentivize further price-reductions, a blended ASP-based payment methodology has the distinct advantage of accelerating price-based competition. A payment system based on charges reduced to costs, in contrast, does not maximize price-based competition among drug manufacturers because a higher charge for a product will result in a higher cost, regardless of whether the drug charges are reduced to costs by applying the hospital's average CCR or a CCR of 1.0. Further, using a CCR of 1.0 for expensive drugs sets an important policy precedent that CMS will equate charges with costs when a product is very expensive. Such a policy could lead to drug and device manufacturers raising their prices to hospitals for other products in order to make the same argument that a special CCR should be applied to their products. These are all reasons why the FAH has significant concerns about the idea of using a CCR of 1.0 for CAR T-cell products.

Incorporating an ASP-based payment would also roughly harmonize IPPS and outpatient prospective payment system (OPPS) reimbursement for CAR T-cell therapy. Under the OPPS, payment for CAR T-cell therapy drugs is made at ASP plus 6 percent. The extraordinarily high cost of the CAR T-cell therapy drugs creates the risk that the ASP-plus-6-percent payment methodology will far outstrip IPPS payment based on the MS–DRG amount and additional payment amounts based on charges reduced to costs (*i.e.*, a new technology add-on payment and outlier payment). Such asymmetry between OPPS and IPPS reimbursement for CAR T-cell therapy might create a financial incentive for providers to improperly or prematurely shift CAR T-cell therapy cases to the outpatient setting.

As noted above, the FAH opposes creation of a new MS–DRG for CAR T-cell therapy in light of the absence of sufficient, accurate data. Moreover, the requirement that any new MS–DRG be established in a budget neutral manner makes the creation of a new MS–DRG that includes payment for the CAR T-cell therapy product problematic. Once CMS has sufficient data on the cost of CAR T-cell therapy from inpatient hospital claims, the recalibration of relative weights that would result from the creation of a new MS–DRG for CAR T-cell therapy would be primarily driven by the extraordinary cost of the CAR T-cell therapy drugs. The redistributive effect of this process would depress payment for core services in order to provide for payment of CAR T-cell therapy services. In addition, if a new MS–DRG was created for the CAR T-cell therapy procedure codes, the resulting payment amount would vary significantly based on the applicable wage index even though labor costs are a relatively insignificant component of the costs of CAR T-cell therapy care. Significant wage-based variation in IPPS payment amounts for CAR T-cell therapy are simply unsupported where it is drug costs, not wages, that drive the vast majority of CAR T-cell therapy payment. In fact, any MS–DRG payment methodology for CAR T-cell therapy would create a significant patient access problem in rural markets because the use of a wage-adjusted standardized amount would depress CAR T-cell therapy reimbursement in low wage markets even though CAR T-cell therapy drug costs remain the same across markets. If hospitals in low wage markets are acutely underpaid for CAR T-cell therapy drugs, it would not be financially feasible to offer CAR T-cell therapy in these markets, and patients with relapsed or refractory B-cell lymphomas living in low-wage markets would be left without access to this critical therapy.

In light of the foregoing problems with integrating very high-cost drug payments into the MS–DRG payment system, the FAH urges CMS to explore alternative payment methodologies that can be deployed under its exceptions and adjustments authority or through a demonstration program after FY 2020. The FAH would like to work with CMS to develop various options for achieving accurate and appropriate reimbursement of CAR T-cell therapy cases and other inpatient cases involving very high-cost drug products following expiration of new technology add-on payments. This process may identify viable long-range legislative or administrative solutions to the problems associated with reimbursement for high-cost inpatient drug cases, but at a minimum, a demonstration or a temporary exception or adjustment for CAR T-cell therapy reimbursement would provide time to create a cost center for the CAR T-cell drug product and to gather adequate data for weighting any CAR T-cell therapy MS–DRG. ***It is the FAH's view that accurate weighting of an MS–DRG for CAR T-cell therapy necessitates establishing a separate cost center, and an interim payment solution will be required as cost reports are submitted with CAR T-cell therapy drug product data in the new cost center.***

Finally, the FAH strongly opposes the inclusion of unadjusted clinical trial data and the exclusion of high-cost CAR T-cell therapy cases from the data used for any MS–DRG weighting. Based on our analysis of FY 2018 MedPAR cases for MS–DRG 016, there were 159 inpatient, Medicare CAR T-cell therapy cases. A number of these cases were clinical trials, and in many clinical trial cases, the provider may report only a nominal $1 charge on their Medicare claims for the drug products and other items and services that are provided without cost or paid for by the clinical trial sponsor.

In any weighting calculation, these clinical trials should either be dropped or the ASP should be added to these cases to reflect the market cost of the drug product. In addition, we determined that *nearly half* of the non-clinical trial CAR T-cell therapy cases (35 cases) for MS–DRG 016 were excluded because the charges on those cases exceeded the threshold for being

trimmed from the MS–DRG weight calculation. Our review, however, suggests that these charges should not have been trimmed because (1) the inclusion of low-cost clinical trials skewed the data and artificially lowered the trim threshold and (2) the trimmed cases in fact reflect the very high costs of the CAR T-cell therapy drug products and associated care. The resulting weight from this exclusion was 6.5929. Had those 35 cases been included in the weight calculation, the resulting weight would have been 7.1275. ***We request CMS revisit the relative weight calculation to include cases with legitimately high charges as well as excluding or appropriately valuing clinical trial cases where the hospital has no costs for the CAR T-cell therapy drug product.*** We have attached an Excel spreadsheet from Watson Policy Analysis (WPA) with these considerations as Attachment 1 hereto.

In conclusion, CAR T-cell therapy represents both a significant medical advancement for beneficiaries who previously had limited to no treatment alternatives. But, because of the extraordinary drug costs, CAR T-cell therapy also threatens to disrupt IPPS reimbursement through underpayment of CAR T-cell therapy cases (particularly in rural markets) and/or the redistribution of payment from basic hospital services to CAR T-cell therapy drugs unless an adequate add-on payment is provided. ***In order to preserve access to care while also maximizing price-based competition among CAR T-cell therapy drug manufacturers, the FAH recommends adoption of an alternative new-technology add-on payment that is set based on the blended ASP for substantially similar CAR T-cell therapy drugs***. Applying this add-on payment in FY 2020 will provide an opportunity for competition to reduce current prices, for CMS to develop an appropriate demonstration or alternative payment methodology under its exceptions and adjustments authority, and for Congress to explore any appropriate legislative approaches to CAR T-cell therapy payment, if appropriate and necessary.

WAGE INDEX

III.C Verification of Worksheet S-3 Data

The FAH strongly opposes the exclusion of accurate and verifiable wage data for certain general, acute care hospitals based on CMS' belief that the data does not reflect the prevailing market conditions. By statute, the wage index is to be updated based on a "survey . . . of wages and wage-related costs" and the Secretary is required to "measure the earnings and paid hours of employment by occupational category." 42 U.S.C. § 1395ww(d)(3)(E). The statute provides no discretion for the Secretary to second-guess the appropriateness of wages actually paid by hospitals or to determine the reasonableness of wages by fiat, particularly on an *ad hoc* basis. In the Proposed Rule, the Secretary identified and excluded eight (now seven) hospitals (the "Seven Hospitals") that are all part of the same health system. 84 Fed. Reg. at 19375. The Secretary does not identify any concerns with the accuracy or verifiability of these Seven Hospitals' wage index data, but nonetheless "do[es] not believe that the average hourly wages of these [seven] hospitals accurately reflect the economic conditions in their respective labor market areas during the FY 2016 cost reporting period." *Id.* at 19376. These hospitals appear to have been singled out for exclusion because the health system to which they belong negotiates its labor contracts with unions on a regional basis in California and the "average hourly wages of these [seven] hospitals differ most from their respective" Core-Based Statistical Areas ("CBSAs"). *Id.* at 19375-76. ***This is not an appropriate rationale for excluding accurate wage index data, and the exclusion of the Seven Hospitals' data without any definable standards creates uncertainty for all hospitals whose salary negotiations could later be second guessed for "reasonableness."***

The exclusion of the Seven Hospitals' wage data based on the Secretary's assessment of the economic conditions in their respective labor market areas is impermissible under 42 U.S.C. § 1395ww(d)(3)(E) and improperly substitutes CMS' judgment of reasonable wage levels in lieu of actual, free-market wage data. Subsection (d)(3)(E) does not contain any standards for the exclusion of accurate data that the Secretary deems to be too high, nor has the Secretary created any such standards.[1] Rather, it appears the Secretary is making *ad hoc* determinations as to the reasonableness of wages. For example, the Proposed Rule originally identified eight hospitals for exclusion but subsequently and without explanation, re-incorporated the wage data for one of the eight hospitals into the April 30, 2019 Public Use File.

Fundamentally, 42 U.S.C. § 1395ww(d)(3)(E) does not give the Secretary the authority to second-guess the wages actually and lawfully paid by a hospital. Instead, subsection (d)(3)(E) appropriately defers to actual market conditions by instructing the Secretary to update the wage index based on "a survey . . . of the wages and wage-related costs." The fact that wages are, in many markets, influenced by labor negotiations does not render the resulting wage data any less valid. Rather, the actual wages paid by a hospital (however such wages are negotiated) has a real and discernable impact on the labor market in that area and is the best evidence of the relative hospital wage level in the geographic area. Put simply, a hospital that is seeking to recruit and retain high-quality employees must reckon with the influence of the highest-paying hospital in its labor market. In the case of the hospitals that compete with the Seven Hospitals for labor, these competitor hospitals have had to respond to the market impact of the Seven Hospitals' FY 2016 wages over the past three years in ways that would be wholly ignored by the exclusion of wage index data for the Seven Hospitals. Moreover, CMS' authority under subsection (d)(3)(E) does not permit it to upend labor policy under the National Labor Relations Act and ignore or artificially suppress the actual market impact of legally protected collective bargaining activities. CMS' responsibility is to survey wages and wage-related costs, not establish or modify such wages.

Even if the Secretary has the discretion to exclude accurate and verifiable wage index data on the basis of a "reasonableness" standard, the Secretary has not created such a standard through formal notice-and-comment rulemaking as required under the Administrative Procedure Act and the Medicare Act. *See* 5 U.S.C. §553; 42 U.S.C. § 1395hh. *Allina Health Services v. Price*, 863 F.3d 937, 944 (D.C. Cir. 2017) *affirmed by Azar v. Allina Health Services*, No. 17-1484 (U.S. Supreme Court Jun. 3, 2019) ("[T]he Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement. . . . [o]n the contrary, the text expressly *requires* notice-and-comment rulemaking."). Even after publication of the Proposed Rule, hospitals lack any ability to understand whether and when the wages they pay might be subject to exclusion on the basis of CMS' *post hoc* assessment of the reasonableness of those wages. It is unclear whether all collectively bargained wages are at risk, or if there is a cut-off for the differential between the hospital's wages and the average wages in the CBSA. It is also unclear whether high wages that are not collectively bargained are at risk for exclusion based solely on the differential between the average wages in the CBSA and the hospital's actual wages.[2] The reference in the Proposed Rule to the Seven Hospitals' association with a managed

[1] The Secretary has previously understood and interpreted Section 1395ww(d)(3)(E) to require that the data from all hospitals in operation be included in the wage index. *See e.g.*, 59 Fed. Reg. 45,330, 45,353 (Sept. 1, 1994) (explaining that terminated hospitals should not be eliminated from the wage index computation because CMS has "always maintained that any hospital that is in operation during the data collection period should be included in the database, since the hospital's data reflects conditions occurring in that labor market area during the period surveyed.").

[2] Notably, hospitals actively compete with each other to hire or retain employees and are subject to the Sherman Act and other state and federal antitrust laws. As the Department of Justice and Federal Trade

care organization and integrated delivery system creates further uncertainty in understanding whether and when actual wages are at risk of exclusion as "unreasonable." Moreover, CMS has not had the benefit of stakeholder input (and appears to have not consulted with the National Labor Relations Board, the Department of Justice's Antitrust Division, or the Federal Trade Commission) on the appropriateness of any standard for excluding actual wage data from general, acute-care hospitals.

Finally, the exclusion of the Seven Hospitals' wage data would have far reaching consequences that do not appear to have been considered by the Secretary. The regulatory impact analysis in the Proposed Rule does not include the required analysis of the impact of this exclusion or assess it against alternative approaches. While the exclusions will harm IPPS hospitals and beneficiary access to inpatient care, they will also significantly harm inpatient psychiatric facilities ("IPF"), skilled nursing facilities ("SNF"), inpatient rehabilitation facilities ("IRF"), and other provider types whose payments are impacted by the wage index. The Secretary has also failed to consider the downstream impact on Medicare Advantage rates paid to health plans and providers that may currently contract based on the Medicare fee schedules. The ultimate result is a significant decrease in reimbursement to the Seven Hospitals, their competitors, and IPFs, SNFs, and IRFs which care for some of the most vulnerable and complex patients.

For all of the above reasons, the FAH strongly opposes the Secretary's proposal to exclude the Seven Hospitals' accurate and verifiable wage data.

III.N.3 Proposals to Address Wage Index Disparities

The FAH applauds CMS's recognition of the negative feedback loop the wage index creates for low wage hospitals and strongly supports CMS addressing this critical problem that disproportionately impacts rural hospitals through an increase to the wage index values of low wage index hospitals. The FAH, however, prefers that this policy be implemented in a non-budget neutral manner under subsection (d)(5)(I).

Rural hospitals play a critical role in ensuring access to care for the approximately 60 million Americans that live in rural areas across the United States. Dependence on rural hospitals is particularly acute for Medicare beneficiaries—close to one-quarter of Medicare beneficiaries live in rural areas and depend on rural hospitals for care.[3] Because Medicare beneficiaries disproportionately rely on rural providers to access care, Medicare reimbursement tends to have a greater influence on rural hospitals' revenue as compared to non-rural hospitals. The wage index, however, has aggravated rather than ameliorated financial problems for many rural hospitals. As CMS observes, the wage index has created a "downward spiral" whereby low wage index hospitals receive lower reimbursement, which decreases their ability to invest in recruiting and retaining employees, which then further depresses reimbursement. This problem is compounded by other market and social factors that contribute to an aging rural workforce. As a result, Medicare beneficiaries in rural areas encounter what CMS has described as "a stretched and diminishing rural workforce." CMS Rural Health Strategy (May 8, 2018).

The FAH believes that CMS policy should take into account the acute problems faced by rural hospitals and ensure that Medicare reimbursement formula do not operate to magnify the

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Commission have noted, "wage-fixing" arrangements "are per se illegal under the antitrust laws." *See* Department of Justice and Federal Trade Commission, *Antitrust Guidance for Human Resource Professionals*, p.3 (Oct. 2016).

[3] MedPAC June 2018 Data Book, Section 2: Medicare Beneficiary Demographics (July 20, 2018).

stress on the rural health delivery system and access issues faced by rural Medicare beneficiaries. Therefore, the FAH supports CMS' proposal to increase the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals. This policy would help those hospitals that have been most severely impacted by the wage index's negative feedback loop to make much needed investments in their labor forces.

The FAH, however, prefers that the proposed increase in the wage index values for these hospitals be implemented in a non-budget neutral fashion. As the Secretary notes, the proposal to provide relief for low wage index hospitals can be implemented under the Secretary's exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I). Subsection (d)(5)(I) permits non-budget neutral implementation, which would ensure that hospitals in the top quartile remain able to respond to market conditions that are largely outside of their control. And the proposed rule offers no indication that the wage index values associated with these hospitals does not accurately reflect their labor costs.

In addition, a non-budget neutral wage index fix for rural hospitals would ensure that hospitals in the middle two quartiles are not adversely impacted by the adjustment to the lowest quartile of wage index values. The Secretary notes that a "key merit" of instituting the wage compression proposal in a budget neutral manner is that hospitals in the middle two quartiles will not be negatively impacted. The FAH agrees that these hospitals should not be adversely impacted, but is concerned that a budget neutral increase to the wage index values for hospitals in the lowest quartile may adversely impact these hospitals if it increases the amount of the budget neutrality adjustment factor to the FY 2020 standardized amount that is needed to implement the important transition policy, which the FAH supports (as discussed below). The adjustment to the standardized amount is proposed to pay for the critical stop-loss transition for hospitals that, due to the combined effect of the proposed changes to the FY 2020 wage index, would otherwise experience a reduction in the wage index of more than 5 percent in FY 2020. Implementing the adjustment to low wage index values in a non-budget neutral manner would reduce the amount of the budget neutrality adjustment to the standardized amount that could otherwise occur, thereby holding hospitals in the middle quartile truly harmless for this much-needed adjustment to reimbursement for low-wage index hospitals.

The Proposed Rule also sets forth three alternatives considered, none of which are supported by the FAH. Under the first alternative, a budget neutrality adjustment would be applied to the standardized amount to offset the cost of adjusting the wage index values of the low wage index hospitals. This would harm all hospitals, particularly those in the middle two quartiles. The second option would increase the amount by which the wage index values for high wage index hospitals are reduced, producing a positive adjustment to the standardized amount, and the FAH does not support this significant and unnecessary redistributive policy. The third option would adopt a national rural wage index area, which would only redistribute wage index values between rural areas with high and low wage index values. Rural hospitals in high wage index areas should not bear the burden of the critical adjustment to reimbursement for rural hospitals in low wage index areas. Instead, the FAH believes that CMS has the authority to increase the wage index values of low wage index hospitals without adversely impacting other hospitals by adopting a non-budget neutral adjustment under subsection (d)(5)(I).

III.N.3.d Proposed Transition for Hospitals Negatively Impacted

The FAH also supports CMS's proposal to adopt a transition wage index to help mitigate significant decreases in the wage index values of hospitals due to the combined effect of the proposed changes to the FY 2020 wage index. While the proposed 5-percent cap on any

decrease in a hospital's wage index as compared to FY 2019 would appropriately limit what would otherwise be significant downward adjustments for certain hospitals in FY 2020, the FAH recommends a longer transition to support hospitals that may continue to experience a significant decrease. Hospitals engage in long-term financial planning, and transition periods for significant policy changes provide a critical limit on sudden reimbursement changes. In the past, CMS has adopted transition policies that mitigate the adverse impact on wage index changes for hospitals, *e.g.*, 79 Fed. Reg. 50372; 69 Fed. Reg. at 49033–34, and the FAH agrees that a transition policy is appropriate here.

DISPROPORTIONATE SHARE HOSPITAL PAYMENTS

IV.F. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FFY 2020

UC-DSH Calculation of Proposed Factor 3 for FFY 2020

The FAH and its members commend CMS for its efforts over the past several years to: (1) better define the costs of uncompensated care, in particular by including the cost of uninsured discounts into the definition of charity care for Worksheet S-10 ("WS S-10") purposes to be consistent with ACA section 3133's mandate; (2) better define the terms of its instructions to providers for the preparation of WS S-10 so that costs are more accurately and consistently reported by hospitals; (3) allow providers to amend their WS S-10s to comply with CMS's revised instructions; and (4) develop, engage in, and improve an audit process aimed at more accurately allocating and disbursing the uncompensated care fund to providers. Given the relative weights Factor 3 assigns to hospitals, the FAH appreciates CMS's recent efforts to rigorously audit hospitals' reported data to make sure hospitals are reporting costs consistently.

While we again encourage CMS to utilize an audit process similar to the wage index audit process to capture and improve the data for all UC-DSH hospitals, the FAH remains heartened by CMS's diligence and desire to arrive at better data through their audit and review of the FY 2015 WS S-10 cost report data. As a result, we focus our comments below on the issue of whether CMS should use the WS S-10 data from audited FY 2015 cost reports, or the data from the FY 2017 cost reports, in the computation of Factor 3 and the allocation of uncompensated care DSH for FY 2020. We also note separately some confusion in CMS's discussion of whether it is including all-inclusive rate hospitals in the Factor 3 calculation using WS S-10 data, and how CMS will treat aspects of that calculation.

Finally, we also offer brief comments on CMS's proposed calculation of Factors 1and 2.

Analysis of Audited FY 2015 WS S-10 Data and Unaudited FY 2017 WS S-10 Data

The FAH strongly supports CMS's proposal to use audited FY 2015 cost report data in the computation of Factor 3 and the allocation of uncompensated care DSH. On balance, the FAH believes that the extensive corrective actions taken on the FY 2015 WS S-10 data through public comment, additional scrutiny, and CMS audit and review, far outweigh the potential benefit from improved cost reporting instructions in place beginning with FY 2017 cost reports. We describe and analyze the benefits and risks associated with each year below.

First, a review of the Medicare supplemental data files accompanying this proposed rule and FY 2019 proposed rule reveals how the national uncompensated care costs derived from the FY 2015 cost reports have changed over time as a direct result of those FY 2015 cost reports being subjected to public comment, additional scrutiny, and the WS S-10 audit process. As

Table 1 shows, total uncompensated care costs calculated from FY 2015 cost reports for IPPS hospitals that were expected to receive DSH declined nearly 18% between last year and this year.4 The table below clearly demonstrates that CMS's efforts in reviewing and auditing the FY 2015 WS S-10 data, along with additional time for public scrutiny and public comment on the data, has had a significant impact on the national uncompensated care cost.

TABLE 1: TRENDING OF UNCOMPENSATED CARE COST CALCULATED FROM FY 2015 COST REPORTS

CMS FILE/ DATA SOURCE	TOTAL COST	ADJUSTMENT FOR AIRH[5]	COST EXCLUDING AIRH	CHANGE FROM FY 2019 IPPS PROPOSED RULE	PERCENT CHANGE FROM FY 2019 IPPS PROPOSED RULE
FFY 2019 Proposed Rule: Medicare DSH Supplemental Data File	$32,451,322,693	0	$32,451,322,693		
FFY 2019 Final Rule Correction Notice: Medicare DSH Supplemental Data File	$30,210,112,106	0	$30,210,112,106	($2,241,210,587)	-7%
FFY 2020 Proposed Rule: Medicare DSH Supplemental Data File	$28,095,695,107	$1,376,501,147	$26,719,193,960	($5,732,128,733)	-18%

A comparison of the national uncompensated care cost calculated using the *audited* FY 2015 WS S-10 data versus using the *unaudited* FY 2017 WS S-10 data similarly reveals a significant difference—an increase of 18%—as shown in Table 2, below. This difference is significantly higher than would be expected over that two-year period. The Federal Reserve Bank of St. Louis hospital and related service CPI data for the period from the end of FY 2015 to the end of FY 2017 indicates CPI growth for hospital and related services over the 24 months of just under 8.8%. https://fred.stlouisfed.org/series/CUUR0000SEMD#0

[4] We have included in our calculation the additional cost from the all-inclusive rate hospitals that have uncompensated care cost included in the FFY 2020 calculation. In addition, we expect uncompensated care cost for the FY 2015 cost reports to increase from the FFY 2020 proposed to final regulations, based on our review of updated HCRIS data since the development of the supplemental data files that reflect the reversal of some very significant adjustments that occurred prior to these updates. We still expect uncompensated care costs to show a significant decline from the final 2019 amounts.

[5] Factor 3 for All-Inclusive Rate Hospitals (AIRH) was not based on uncompensated care cost for FFY 2019 and their cost was not included in the national uncompensated care cost amount that CMS published and utilized for FFY 2019. For FFY 2020, CMS is planning on utilizing uncompensated care cost for these facilities and has included their cost in the national total. We are removing this cost from the FY 2020 proposed rule for comparison purposes.

TABLE 2: CHANGE IN UNCOMPENSATED CARE COST CALCULATED FROM AUDITED FY 2015 COST REPORTS VS. UNAUDITED FY 2017 COST REPORTS	
Uncompensated Care Cost Calculated from Audited FY 2015 WS S-10 data (from FFY 2020 IPPS Proposed Rule: Medicare DSH Supplemental Data File)	$28,095,695,107
Uncompensated Care Cost Calculated from Unaudited FY 2017 WS S-10 data (from FFY 2020 IPPS Proposed Rule: Medicare DSH Supplemental Data File)	$33,151,527,715
Increase	$5,055,832,608
% Increase	18%

When comparing audited FY 2015 WS S-10 data and unaudited FY 2017 WS S-10 data at the hospital level for hospitals expected to receive UC-DSH payments in FFY 2020, significant discrepancies emerge. Table 3 below shows that 32% of the hospitals that are expected to receive uncompensated care payments had an increase in uncompensated care cost of greater than 25%, and 17% of hospitals had an increase greater than 50%. In addition, 60 hospitals showed increases of greater than $20,000,000.

TABLE 3: CHANGE IN UNCOMPENSATED CARE COST FROM FY 2015 TO FY 2017 COST REPORTS FOR HOSPITALS EXPECTED TO RECEIVE UNCOMPENSATED CARE PAYMENTS IN FFY 2020		
Threshold	**Number of hospitals over threshold**	**Percent of UC-DSH hospitals**
Increased more than 50%	421	17%
Increased more than 25%	780	32%
Increased by more than $20 million	60	2%

This analysis of the relative differences between hospitals' audited FY 2015 data and unaudited FY 2017 data echoes CMS's observations of the significant relative differences between unaudited and audited WS S-10 data. See 84 Fed. Reg. at 19,419, col. 1 ("For example, approximately 10 percent of audited hospitals have more than a $20 million difference between their audited FY 2015 data and their unaudited FY 2016 data.").

Overstatement of Deductible and Coinsurance Reporting in WS S-10 Line 20

Related to the issue of whether to use audited FY 2015 WS S-10 data or unaudited FY 2017 WS S-10 data for Factor 3, the FAH remains concerned that the deductibles and coinsurance reported in WS S-10, line 20, column 2 are overstated in both the FY 2015 and FY 2017 cost reports. Although, as illustrated in Table 4 below, the FY 2015 data shows significant improvement as a result of the additional vetting, public scrutiny, and CMS audit process to which it has been subjected, our analysis indicates this remains an area in need of sustained and additional focus in future audit scoping considerations.

As deductibles and coinsurance are not subject to the application of a cost-to-charge ratio, an error in reporting these amounts can disproportionately distort relative uncompensated care cost more than any other issue. Any error in the reporting of deductibles and coinsurance would misstate uncompensated care cost by the amount of the error. For our analysis below, we subtracted line 25 and payments on line 22, column 2 from line 20, column 2 to arrive at the amounts of deductibles and coinsurance.

While some data anomalies related to deductible and coinsurance appear to remain in the audited FY 2015 cost report data (mostly the result, we suspect, of the FY 2015 WS S-10 audits focusing primarily on hospitals reporting a larger percentage of uncompensated care cost), an unacceptably large number of these chimerical amounts (certainly errors) are present in the FY 2017 W/S S-10 data files and should preclude its use as the allocation basis for UC-DSH in FFY 2020.

TABLE 4: DEDUCTIBLE AND COINSURANCE REPORTING ON WS S-10, LINE 20[6]

Item	2015	2017	Change	Percent Change
Total reported deductibles and coinsurance	$3,554,921,720	$5,569,255,891	$2,014,334,171	57%
Hospitals > $10 million in reported deductibles and coinsurance	47	121	74	157%
Hospitals >$1 million in reported deductibles and coinsurance	844	912	68	8%
Hospitals where deductibles and coinsurance cost exceed cost on uninsured patients	548	576	28	5%
Hospitals where deductibles and coinsurance cost exceed 50% of cost on uninsured patients	572	878	306	54%
Hospitals > $10 million in reported deductibles and coinsurance where deductibles and coinsurance exceed the cost of uninsured patients	25	80	55	220%
Deductibles and coinsurance as a percentage of uninsured patients (national)	24%	34%	10%	42%

6 Data derived from the March 31, 2019 HCRIS file.

Number of cost reports of hospitals expected to receive UC DSH	2,504	2,495	(9)	0%

The significant problems with reporting of deductibles and coinsurance in FY 2017 provide a glaring example of the residual misreporting of data that remains even after the issuance of improved cost reporting instructions for FY 2017. There was only a minor instruction change for that data element and providers continue to report it incorrectly. Audited data that has been thoroughly vetted and subject to public scrutiny is far preferable and more equitably justifiable than unaudited data where CMS trims only the most aberrant to data.

The Argument that CMS's Limited Hospital Audit of FY 2015 WS S-10s is Less Relatively Reliable than Unaudited FY 2017 Data is Very Flawed

We suspect that CMS will receive comments from some providers that it is fundamentally unfair to use FY 2015 WS S-10 data set because it compares audited with unaudited WS S-10 data, and therefore unaudited data for FY 2017 provides a better relative comparison. This argument is severely flawed for several reasons that we identify as follows. First, as CMS indicates in the proposed rule, while 600 of the DSH hospitals were subject to the audits of FY 2015 data, those 600 hospitals receive 50 percent of the total value of the UC-DSH pool for all hospitals. Thus, from the perspective of how relative relationships in the cost of uncompensated between hospitals are accurately portrayed in the data, this focus was justified. Second, in addition to the MAC audits of the data, CMS applied trims to the data, and issued letters requesting correction of aberrant data to providers. This expanded the reach of CMS in creating comparable data among relevant hospitals in the comparison of the FY 2015 data. Only trims and some recent requests associated with aberrant data to some hospitals have occurred for the FY 2017 data, and it is unclear whether CMS will receive a timely response to the letter requests for its use as part of this rulemaking. Additionally, the results of those steps to correct the FY 2017 data will not be available for public scrutiny and comment in the final rule. Past experience suggests that public scrutiny, through comment, of the uncompensated care data before its use for the first time assists CMS in making use of the data to distribute uncompensated care payments. FAH recommends that CMS only use data that has been subject to public scrutiny (as it does for the wage index) before distributing nearly $8.5 billion in FY 2020 uncompensated care payments.

Finally, FY 2017 S-10 data was subject to a new set of instructions, and as we have learned from a review of the S-10 data since 2013, providers have varied interpretations of how to report data every time instructions change. This is not to suggest the new instructions are not welcome and were not necessary, as they certainly were and are appropriate. But as the history of reporting the data has taught us, there can be as many interpretations of a new instruction that has not been subject to audit and education as there are providers.

As the above analyses demonstrate, the unaudited FY 2017 cost report data is simply not ready to use as the allocation basis for uncompensated care payments. Given the timing of the FY 2015 WS S-10 audits and the deadlines for cost report filing for FY 2017, hospitals were not afforded an opportunity to apply lessons they might have learned through the audit process to their FY 2017 cost reports. Many hospitals that might desire to reopen a FY 2017 cost report based on their FY 2015 audit findings have not had time to even start that process. And the

audits of FY 2017 data will not be complete in time for FY 2020. For FY 2021, after thorough audit and review of the FY 2017 WS S-10 cost report data over the next year, the FY 2017 data likely will be more suitable to use as the allocation basis. To further ensure the reliability of FY 2017 data, the FAH also suggests that CMS indicate in the FY 2020 Final Rule the agency's intention to use FY 2017 WS S-10 data in calculating Factor 3 in FY 2021, so providers will begin amending their as-yet unaudited FY 2017 WS S-10 data in earnest.

The Change to Use of a Single Year of Data

While the FAH supports using audited WS S-10 data for allocating UC-DSH payments, and thus supports CMS's proposal to use the single available year of audited data (FY 2015 cost reports) for FY 2020, the FAH notes that the use of multiple years of audited data would tend to smooth over any remaining anomalies in the data and thus result in more accurate allocation of UC-DSH payments in future years. We may in the future support an alternative that uses multiple years of data.

Confusion in the Proposed Rule Notice About How All-Inclusive Rate Hospitals Will be Included in the Factor 3 Calculation

CMS indicates on consecutive pages of the proposed rule, concerning whether, for the first time, WS S-10 cost data will be used to calculate Factor 3 for all-inclusive rate hospitals, that:

"We have examined the CCRs from the FY 2015 cost reports and believe the risk that all-inclusive rate providers will have aberrant CCRs and, consequently, aberrant uncompensated care data, is mitigated by the proposal to apply trim methodologies for potentially aberrant uncompensated care costs for all hospitals. Therefore, we believe it is no longer necessary to propose specific Factor 3 policies for all-inclusive rate providers. [86 Fed. Reg. at 19420, col.3 (emphasis added)].

> Step 1: Remove Maryland hospitals. In addition, *we would remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals*. [86 Fed. Reg. at 19421, col.2 (emphasis added)]."

These are directly contrary statements indicating WS S-10 data will be used with trims to calculate Factor 3 for all-inclusive rate hospitals and, that such hospitals will be excluded from the Factor 3 calculation using such data. CMS needs to provide a consistent statement in the final rule.

As a practical matter, the supplemental data files provided with the proposed rule indicate that CMS is in fact using the WS S-10 data to calculate all-inclusive rate hospitals' Factor 3s. We then reviewed the all-inclusive rate hospitals with very high CCRs, as these were most likely to have their CCRs subject to trims. We identified twelve very high CCR all-inclusive rate hospitals that had no trims applied to their CCR data on WS S-10. Eleven of those twelve hospitals are in New York state. This makes very clear to us that the CMS basis for its change in position on using WS S-10 data to calculate Factor 3 for all-inclusive rate hospitals, "the risk that all-inclusive rate providers will have aberrant CCRs and, consequently, aberrant uncompensated care data, is mitigated by the proposal to apply trim methodologies for potentially aberrant uncompensated care costs for all hospitals," is not in fact correct. CMS clearly did not apply data trims to these hospitals' CCRs to align their aberrant costs with those of other hospitals. We

encourage CMS to revisit its trims in the final rule for these hospitals, and also to focus its audit activity on the FY 2017 WS S-10 data during the next year on whether high CCR hospitals, particularly those that use an all-inclusive rate structure, are generating an accurate portrayal of uncompensated care costs.

UC-DSH Calculation of Proposed Factors 1 and 2 for FFY 2020

We have only a brief comment that relates to the calculations of both Factors 1 and 2 for FFY 2020. Factor 1 is the calculation of what Medicare would have paid under the law that predated the amendments to the DSH payment methodology. An aspect of that calculation concerns the growth or decrease in the Medicaid population, because the size of the Medicaid population can affect the calculation of traditional Medicare DSH payments nationally. Similarly, the Factor 2 calculation is driven by the increase or decrease in the uninsured population, and that population includes Medicaid enrollees.

While CMS is projecting an increase in the Factor 1 calculation from FYs 2019 to 2020, from $16.275 to $16.857 billion, CMS is applying an "Other" adjustment factor of 0.9932 that suppresses its projection FY 2020 DSH payments. 86 Fed. Reg. at 19410. The "Other" is a positive adjustment in all the other recent years of the calculation from 2017 through 2019. Id. The lowest amount for the other years is 1.02206. Id. We understand that this "Other" adjustment during these prior periods was intended in part to capture the Medicaid expansion that began in FFY 2014. Thus, it seems, CMS is now projecting an "Other" adjust of less than 1, presumably based on a decrease in the Medicaid population. CMS does not explain the basis for this figure, making it difficult to comment meaningfully on it. If CMS is not projecting a decrease in the Medicaid population, and that is not driving a negative "Other" adjustment, we would like to know what is the basis for this adjustment. The ability to meaningfully comment, especially in the absence of the normal administrative and judicial review available for other regulatory actions under the Medicare Act, requires that CMS provide the values and data underlying the "Other" adjustment.

In prior years and in the current notice, CMS explains why growth of the Medicaid population does not necessarily drive an increase in inpatient services for that increased population, principally because CMS asserts that the new population is healthier than the pre-Medicaid expansion population. Id. at 19411. Thus, CMS will not necessarily increase or decrease Factor 1 because the Medicaid population decreases or increases. But that absence of a direct relationship in calculating Factor 1 is not true in calculating Factor 2. As the Medicaid population decreases, whatever the cause, CMS and OACT must take that projected decrease into account to assess the calculation of Factor 2. For this reason, we additionally request CMS either revise Factor 2 to account for the estimated reduction in Medicaid enrollment as suggested by the 0.9932 "Other" adjustment in determining Factor 1 or explain why such a revision is unnecessary.

QUALITY PAYMENT PROGRAMS

Paperwork and Meaningful Measures Initiatives

In FY 2019 IPPS/LTCH PPS final rule CMS adopted a measure removal factor policy in the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Value-Based Purchasing (HVBP) Program. In the FY 2020 IPPS/LTCH PPS proposed rule CMS is proposing to adopt the same measure removal factors policies in the Hospital Readmissions Reduction

Program (HRRP) and Hospital Acquired Condition (HAC) Reduction Program. Specifically, CMS proposed to adopt a set of eight quality measure removal factors for the HRRP and the HAC Reduction Program. The FAH strongly supports CMS's proposal to add the eight measure removal factors to the HRRP and HAC programs.

The FAH commends CMS for its proposed continued application of the Meaningful Measures framework to the HRRP and HAC program allowing the agency to prioritize and reduce the number of quality measures across the quality programs. This addresses our previously expressed concerns about the burden of managing many measures and the unnecessary duplication of measures across programs.

IV.G Hospital Readmissions Reduction Program (HRRP)

The HRRP imposes reduced payments of up to 3.0 percent of base operating DRG payments for hospitals having readmission rates for certain conditions that exceed expected rates. For FY 2020 CMS proposes minor updates to the program.

Dual-eligible Look-Back Period

In FY 2019 CMS implemented a new readmission formula under which hospitals are stratified into five peer groups based on the proportion of patients they serve who are Medicare-Medicaid "dual-eligible" for purposes of determining the HRRP payment adjustment. "Dual-eligibles" are identified using the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged from the hospital. Currently, there is there is a risk of undercounting the dual eligible status of beneficiaries who die in the month of a hospital discharge since that leads to its status not being recorded or changing from dual to non-dual. **The FAH supports CMS's proposal to modify the definition of "dual-eligible" to identify patient beneficiaries who die in the month of discharge using a one month lookback period sourced from the State MMA files.**

FAH members have a long-standing belief that additional risk adjustment should be used to address social risk factors, in particular for readmissions and other outcome measures used in payment programs. The FAH believes the stratification approach that began in FY 2019 for the HRRP is a reasonable first step for addressing social risk factors. However, our members urge CMS to continue to analyze the impact of social risk factors on hospital readmission rates and to improve the risk adjustment of the readmission measures to account for social risk factors beyond dual eligibility status. While dual eligibility status is a reasonable initial proxy, CMS should undertake a more direct assessment of the effects of social risk factors through risk adjustment of the readmission measures to account for specific factors that are known to affect readmission rates and that are beyond the hospital's control. These may include community characteristics such as availability of healthcare providers and access to pharmacies and transportation as well as patient-level information such as education and language proficiency. The presence of State Certificate of Need laws and regulations should also be considered.

Subregulatory Process for Non-Substantive Changes to Payment Adjustment Factor Components

CMS has previously adopted a subregulatory process for making non-substantive modifications to HRRP measures specifications. It now proposes a similar sub-regulatory approach for updates to the HRRP payment adjustment factors including dual proportion, peer group assignment, peer group median ERR, neutrality modifier, and ratio of DRG payments to total payments, among others, to determine hospital payments in each fiscal year. CMS would make the determination of when a change is substantive or non-substantive on a case-by-case basis.

The FAH applauds CMS's effort to improve efficiency. However, we remain concerned about risks to transparency. ***The FAH supports a subregulatory process so long as CMS specifies a clear definition of what non-substantive constitutes, and criteria on the definition of a non-substantive change are made available. Also the FAH encourages CMS to always err on the side of making the determination that a change is substantive if the criteria do not apply or if there is any doubt so that stakeholders not be deprived of the opportunity for notice and comment.***

IV.H. Hospital Value-Based Purchasing (VBP) Program

NHSN HAI Measure Data

CMS proposes that the Hospital VBP Program will use the same data used by the HAC Reduction Program for purposes of calculating the Centers for Disease Control and Prevention (CDC) National Health Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures beginning with CY2020 data collection. The FAH supports the use of the same data and validation requirement.

IV.J.2. Critical Access Hospitals (CAHs) as Nonprovider Sites for Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Payment Purposes

The FAH supports CMS's proposed policy to consider critical access hospitals (CAHs) as nonprovider sites for purposes of direct GME and IME payment purposes in order to better support residency training in rural and underserved areas. Under current policy, CAHs are not considered nonprovider settings, and therefore, a hospital cannot include residents training in a CAH in its full-time equivalent (FTE) resident count. The FAH shares the concern that this policy has an adverse effect on training in rural and underserved areas, particularly with respect to primary care and community-based training programs, and may also hinder joint hospital-CAH efforts to recruit and retain physicians in rural communities. CAHs currently have the option of incurring the costs of training residents in approved residency programs and receiving payment at 101 percent of the reasonable costs incurred, but this is not a viable option for many CAHs due to size or financial considerations. Although the statute uses the term "nonprovider" rather than "nonhospital," 42 U.S.C. § 1395ww(d)(5)(B)(iv)(II) and (h)(4)(E), the term "nonprovider" is not defined in the Medicare Act, and the FAH concurs with CMS's assessment that the terms "nonprovider" and "nonhospital" have been used interchangeably, such that the statute leaves some ambiguity as to whether a CAH may be considered a nonprovider site. Therefore, CMS has the discretion to change its policy on this matter, and the FAH fully supports treating CAHs as nonprovider sites in order to better support rural health.

LONG-TERM CARE HOSPITALS PPS

VII.C. LTCH Discharge Payment Percentage Reimbursement Changes

CMS is proposing new regulations at 42 C.F.R. § 412.522(d)(3) to (6) to implement the requirement 42 U.S.C. § 1395ww(m)(6)(C)(ii) that, for cost reporting periods commencing on or after October 1, 2019, any LTCH with an LTCH "discharge payment percentage" of under 50 percent (i.e., at least fifty percent of the LTCH's discharges are not paid under LTCH PPS), will be advised of such occurrence and will be paid in successive cost periods for all discharges the payment amount that would have been paid to an IPPS (subsection (d)) hospital for that discharge, subject to a "process for reinstatement." CMS proposes, specifically, that starting with cost reporting periods beginning in FFY 2020 and after, LTCHs that are subject to this

payment penalty will receive payment for all discharges at the amount comparable to the IPPS amount as determined under 42 C.F.R. § 412.529(d)(4)(i)(A) and (d)(4)(ii), with an additional payment for high-cost outlier cases based on the IPPS fixed-loss amount, subject to a multi-year probationary "reinstatement" process.

Whereas the proposal to shift payment to comparable amounts under the IPPS for all discharges in subsequent years by providers with a discharge payment percentage of less than 50 percent is generally consistent with the governing statutory provisions, the proposed mechanics of the application of this requirement, and particularly, the proposed mechanics of the special probationary reinstatement process, raise several issues of concern to FAH, that we recommend CMS address in the final rule.

The Proposed Probationary Reinstatement Process Is Too Long and Introduces Too Great a Degree of Uncertainty from Year to Year with Respect to LTCH Reimbursement

The FAH agrees with CMS's proposal to allow providers a "second chance" to show compliance with the discharge payment percentage requirement, but asks CMS to consider changes that would shorten and simplify the reinstatement process. CMS's proposed implementation of the 50 percent discharge payment percentage requirement would take too many years to resolve an LTCH provider's reimbursement both prospectively and retrospectively, and further unduly "punishes" providers on a retroactive basis. Such an approach is too cumbersome, too unpredictable for providers, and appears inconsistent with the historical Medicare PPS principles favoring certainty, prompt payments and predictability, so as to allow providers to be able to budget effectively and focus on delivering patient care in the most efficient and effective manner possible.

As currently proposed, an LTCH that falls below the required 50 percent level in Year 1 (for example, any cost reporting year starting on or after October 1, 2019), will be notified of the shortfall in the first half of Year 2, and would then have the second half of Year 2 to show compliance in 5 of the 6 next consecutive months. If that LTCH demonstrated compliance in the second half of Year 2, the provider would continue to be paid under LTCH PPS in Year 3. But, if the LTCH could not show compliance with the 50 percent requirement in the second half of Year 2, the provider would be paid in Year 3 for all discharges an amount comparable to what payment would be under the IPPS. Moreover, as proposed, if the LTCH met the reinstatement test in the second half of Year 2, but then failed to satisfy the payment percentage requirement in Year 3, the provider's reimbursement for Year 3 would then be retroactively adjusted upon cost report settlement (sometime in Year 4 or more likely in Year 5 or even years later) by the MAC to reflect payments for all discharges in Year 3 that would be comparable to payments for those discharges under the IPPS. Such a "probationary" process potentially relegates LTCHs participating in the reinstatement process to a payments "limbo" for up to several years with respect to these providers' discharges, and unduly punishes LTCHs for years after the provider's failure to hit the 50 percent level in Year 3, even though it satisfied CMS's reinstatement process in Year 2 of the cycle.

1. CMS should modify the proposed probationary reinstatement process so that it is identical to, or closely resembles, the cure period that CMS utilizes when determining an LTCH's compliance with the 25-day average length of stay (ALOS) requirement. Such a revision, alone, would ameliorate multiple problems with the proposed probationary reinstatement process. Under the 25-day ALOS test, if an LTCH is out of compliance in one year, the onset of any change to LTCH status is delayed for one year (to Year 3), to allow the

LTCH to demonstrate (in the second year) that it meets the 25-day ALOS requirement in at least 5 out of the immediately preceding 6 months. See, 42 C.F.R. 412.23(e)(3)(ii) and (iii). CMS noted, in re-adopting this policy in the 2005 LTCH PPS Final Rule, that there can be fluctuations in discharges and patient census within any given year, and that LTCH providers should have an opportunity to present their most recent data. See, 69 Fed.Reg. 25,673, 25,706 (May 7, 2004).

The same considerations should apply to the 50 percent discharge payment requirement. Small variations in an LTCH's patient population can have a dramatic impact on the provider's ability to comply with that requirement. It follows that CMS should implement an "up or down" cure period, applicable to the year following (Year 2) the one in which an LTCH fails to reach the 50 percent payment threshold. Under such test, a MAC would judge the LTCH's compliance using a five months out of six review. If the LTCH re-demonstrates compliance with the 50 percent rule, the LTCH would then be eligible for payment in Year 3 under the LTCH PPS for qualifying discharges. If the LTCH cannot demonstrate compliance, the LTCH would be placed on IPPS payment for all discharges in that Year 3.

FAH sees no valid reason for an LTCH that shows compliance for 5 out of 6 months in Year 2 to then be subjected to a "look back" period in and after Year 3, and to remain uncertain as to what its Year 3 and subsequent years' payments will be for at least two and potentially many more years later. Use of the 25-day ALOS cure period is time tested and has proven to be effective. Implementation of a similar cure or "reinstatement" period for the discharge payment requirement — without the complexity and uncertainty of a probationary period and its attendant delay — should similarly produce reliable results, and would be simpler to apply for all concerned. Moreover, there is no real risk of manipulation or gaming where a provider is governed by the constraints of patients' needs (admissions and discharges occur when medical criteria dictate) and the Medicare program's prompt billing requirements, which do not permit providers to hold billing for extended periods of time. As a practical matter, it would be odd for an LTCH to hold bills and artificially depress revenue for any given six month or one year period. Providers have a strong if not overriding interest in getting paid on a timely basis.

Likewise, CMS should modify its proposal to avoid the need and likelihood of punitive, retroactive adjustments. Simply stated, the MAC's application of the 50 percent discharge payment percentage test in Year 2 should finally determine an LTCH's Year 3 payment type status. If a probationary period is used, where a MAC looks back after Year 3 is completed, the process can realistically be expected to drag on for years. By the time a MAC actually settles the Year 3 cost report (which, itself, is not filed until 5 months after the end of the fiscal year), the review process most likely will not take place until Year 5, at the earliest, and given that MACs are often backed up with reviews as it is, perhaps until Years 6, 7 or even 8. FAH does not believe that such a long, drawn out test and adjustment period should be adopted by CMS. It makes unnecessary work for MACs, potentially extends even routine reviews for many years, and will be demonstrably punitive to LTCH providers.

Providers of all types, including LTCHs, require some basic predictability and certainty with which to forecast financial needs and foster budgetary stability, and to plan even one year ahead. When a provider demonstrates compliance over a 6 month period with the 50 percent discharge payment percentage rule, that provider should be able to rely on that result for the next cost reporting period. Where an LTCH's every discharge in "Year 3" of a cycle is at risk, for years in the future, of being significantly "re-priced," and subsequent years are thereby impacted as well, the reinstatement process will hamstring an LTCH's ability to function, upgrade equipment and provide needed care. The cure period used already with respect to the 25-day

ALOS review is rational, effective and predictable. A similar system should be adopted by CMS to test compliance with the 50 percent discharge payment requirement.

2. If CMS retains the retroactive payment adjustment process in the final rule, the retroactive adjustment process should address underpayments. FAH does not agree with CMS's proposed retroactive adjustment process covering a "Year 3" where an LTCH had previously satisfied the 6 month reinstatement test in Year 2. But if CMS nonetheless retains such a process, there must be a corresponding process to incorporate ***underpayments*** in Year 3 as well. Where an LTCH is being paid under IPPS during a "Year 3" (based on the LTCH's failure to meet the discharge payment percentage in Year 1), the MAC will determine whether the LTCH met the 50 percent threshold for Year 3 sometime in the first half of Year 4. If the LTCH is found to have actually met the 50 percent threshold in Year 3, then the LTCH should be adjusted upward at that time for its Year 3 discharges, to assure that all qualifying LTCH discharges are actually paid under the LTCH PPS. An LTCH should not be subject to a downward adjustment in Year 3 (by reason of failing to meet the 50 percent test in the second half of Year 2), without also being subject to an *upward* adjustment in Year 3 (by reason of actually exceeding a 50 percent LTCH payment percentage in Year 3). A provider should not have to wait until Year 4 or Year 5 to be adjusted back to the LTCH PPS.

3. The proposed reinstatement and retroactive adjustment process "punishes" providers twice for failing to meet the required 50 percent discharge payment percentage in one year. FAH objects to the proposed structure of the reinstatement process, in addition, because it "punishes" an LTCH provider twice, for the same "miss." Once a payment adjustment is applied (for example, in Year 3), the Year 3 results are not reviewed by a MAC until Year 4. Meanwhile, not only is the LTCH paid at IPPS comparable rates during Year 3, but the proposed rule indicates that the LTCH will stay on IPPS rates for the entirety of Year 4 as well, even though the MAC may have determined that the LTCH actually met the 50 percent threshold in Year 3, or was subsequently determined to be meeting the 50 percent discharge payment percentage requirement in Year 4. This means that the LTCH deemed out of compliance will be paid like an IPPS hospital for two full cost reporting periods, even though the LTCH may actually have met the 50 percent test in Year 3 and/or Year 4. FAH contends that such a result is overly punitive, and subjects the LTCH involved to unreasonable financial and operating burdens, if not a risk of surviving as an LTCH provider.

4. CMS should instead require MACs to discontinue the payment adjustment as soon as the MAC confirms that an LTCH has complied with the 50 percent discharge payment percentage for the prior full year. If an LTCH is placed on IPPS comparable payments for all discharges in Year 3, once the MAC determines, early in Year 4, that the LTCH was in compliance with the 50 percent requirement in Year 3, the LTCH should immediately be placed back on LTCH PPS reimbursement for Year 4. FAH sees no basis for continuing the downward payment adjustment (in Year 4) once there has been clear evidence of full compliance by the LTCH for Year 3 discharges. Any continued downward adjustment must be supported by evidence of continued non-compliance. There is never a change in classification of the LTCH as a result of non-compliance with the discharge payment percentage requirement, either under the governing statute, or as a part of the proposed regulation. Further, no requirement exists that precludes CMS from discontinuing the payment adjustment for the entirety of Year 4 (based on demonstrated compliance in Year 3), after Year 4 has started.

FAH Believes that Other Revisions Should Be Made to the Proposed Rule to Assure that the 50 percent Discharge Payment Percentage Requirement Is Accurately Calculated, and Applied Consistently and Efficiently.

1. MACs should be required to review all relevant data sources, including but not limited to additional matching claims, before notifying an LTCH that its discharge payment percentage fell short of the 50 percent requirement. Individual LTCHs have no control over when subsection (d) hospitals actually submit their claims. Such short-term acute hospitals have up to a year to submit their claims to Medicare. If an LTCH admission failed to meet the ICU criterion or ventilator simply because the MAC did not see an IPPS hospital matching claim at the time the MAC reviewed the LTCH discharge, this will artificially reduce the LTCH's discharge payment percentage, perhaps even below the 50 percent threshold, solely as a result of differential claims submission timing by the IPPS and LTCH providers. To assure that LTCH discharge payment percentages are not mistakenly or artificially understated, CMS should require its MACs to check for additional matching claims submitted by the referring hospitals before the MAC calculates the LTCH's discharge payment percentage.

For the same reasons, FAH believes that LTCHs should be permitted under the regulation to submit documentation to establish that a patient's LTCH admission was immediately preceded by a qualifying stay in a short term acute hospital and/or that the patient had been treated for at least 3 days in that short term acute hospital's ICU. In light of the draconian sanctions imposed on LTCHs that narrowly fall short of the 50 percent requirement, FAH believes it is critical to assure the accuracy of the calculation of each LTCH's discharge payment percentage. Allowing LTCHs to submit proof of qualifying criteria *in advance of any MAC notification* would provide an efficient and more reliable vehicle for assuring the accuracy of the MAC's calculation. Further, CMS should clarify in the final rule precisely what documentation of a prior hospital stay will be needed to establish that each LTCH discharge is payable under the LTCH-PPS.

2. CMS should clarify that the discharge payment percentage will be applied to multi-campus LTCHs only once, for the single provider number of the multi-campus LTCH. For most purposes, the Medicare program considers separate campuses of one hospital to be different practice locations of one hospital. The 50 percent discharge payment percentage requirement should be applied to each hospital, since that is how the provider is organized and certified. To do otherwise will subject single hospitals to reviews that yield inconsistent results.

3. CMS should clarify on what basis LTCHs will be reimbursed a "comparable IPPS amount." In the proposed rule, CMS indicates that payments to an LTCH that have been reduced under Section 412.522(d)(4) will be made at an amount comparable to the IPPS payment amount, as determined under Sections 412.529(d)(4)(i)(A) and (ii) [referencing the short-stay outlier ("SSO") regulation]. CMS proposes further that discharges will be eligible for high cost outlier payments based on the IPPS fixed-loss amount. CMS notes that the IPPS-comparable amounts contemplated for LTCHs not meeting the discharge payment percentage requirement will be similar to those used for SSOs. The SSO regulation suggests that the proposed payment amount to be used for LTCHs that are out of compliance with the discharge payment requirement will be equal to the full IPPS payment rate (operating and capital) for the patient's Medicare severity diagnosis related group. However, CMS then states that the calculation under Sections 412.529(d)(4)(i)(A) and (ii) will be on a *per diem* basis, which somewhat inconsistently implies that LTCHs being paid IPPS comparable amounts under Section 412.522(d)(4) could be paid on a *per diem* basis. FAH requests CMS to clarify that LTCHs which are out of compliance with the discharge payment percentage requirement will, in fact, receive a payment for each

discharge that is truly comparable to the full IPPS payment applicable to such discharge (and not be paid on a *per diem* basis).

4. CMS should require a public comment period prior to adopting any sub-regulatory guidance establishing procedures for evaluating LTCH compliance with the discharge payment percentage requirement. Whereas CMS states in the proposed rule that it intends to utilize sub-regulatory guidance to establish specific procedures for reinstatement under the probationary process, FAH requests that CMS provide a public comment period prior to any such adoption. The reach and import of the discharge payment percentage requirement constitutes a major change in CMS's approach to reimbursing LTCHs for services. The degree of risk to LTCHs of these changes is monumental. FAH believes that it is critical for CMS and LTCH providers to have the "full dialogue" afforded under a 60 day public comment period prior to the implementation of new procedures governing enforcement of the discharge payment percentage requirement.

5. CMS should confirm that LTCHs have a right to appeal any finding of non-compliance with the discharge payment percentage requirement. Given the magnitude of the impact of placing an LTCH provider on IPPS payments (instead of LTCH PPS payments) for all discharges, for at least one and possibly more years, FAH believes it is critical that LTCHs are explicitly advised that a MAC's determination of non-compliance be identified as an appealable "final determination" under Medicare regulations. There is nothing in the statute or regulations that would prohibit such a characterization. But a clarification is needed, since the determination will in some cases be made before submission of a cost report for the year affected, and certainly in some cases before a MAC finally settles that cost report.

Addendum V.D.4. Budget Neutrality Adjustment (BNA) for Site Neutral HCO Cases

CMS also proposes to continue to apply a BNA reduction factor of 5.1% under section 412.522(c)(2)(i) to all cases paid at the site neutral payment rate (including the site neutral payment rate portion of blended rate payments for FY 2020 discharges occurring in LTCH cost reporting periods beginning before October 1, 2019) so that HCO payments for site neutral cases will not result in any change in estimated aggregate LTCH PPS payments.

The FAH strongly disagrees with CMS's proposal to apply an additional 5.1% BNA for site neutral cases that qualify as high-cost outliers. As the FAH explained in previous years' comments, this BNA is duplicative and unwarranted because CMS has already applied budget neutrality adjustments to reduce the operating and capital portions of the IPPS standard Federal payment rate by the same 5.1%, before using that rate to determine the IPPS comparable per diem amount for site neutral payment cases.

The IPPS comparable per diem amount, as determined under section 412.529(d)(4), is "based on the sum of the applicable operating inpatient prospective payment system standardized amount and the capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge."[7] CMS claims that a separate BNA for LTCH site neutral HCO cases will "reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems." 84 Fed. Reg. at 19,617. However, by aligning this proposed policy with the IPPS payment system—and making the IPPS comparable per diem amount and the IPPS fixed-loss amount the primary

[7] 42 C.F.R. § 412.529(d)(4)(i)(A).

components—CMS also is required to consider the adjustments that it has already made to the proposed IPPS and capital PPS payment rates to account for outlier payments. And, as noted earlier, CMS already reduced the operating standardized payment amount under the IPPS and the capital federal rate under the capital PPS for outliers. As CMS explains, these 5.1% (IPPS) and 5.34% (capital) outlier adjustment factors, respectively, already reduce the IPPS and capital PPS payment rates. Id. at 19,598–99.

MedPAC's prior May 31, 2016 comment letter states that CMS should not apply a separate budget neutrality adjustment to site neutral high-cost outliers because "the IPPS standard payment amount is already adjusted to account for HCO payments."[8] The FAH agrees with MedPAC that this BNA is duplicative and should not be applied. CMS should only adjust LTCH site neutral payments once for outlier budget neutrality.

CMS's unwillingness to address these issues directly the past few years requires that we raise them again for further consideration this year. The FAH asks that CMS acknowledge these concerns, as it appears incorrect for CMS to have applied the 5.1% (0.949) site neutral HCO BNA to FY 2016, FY 2017, FY 2018, and FY 2019 site neutral payments for the same reasons that CMS should not apply this BNA to FY 2020 site neutral payments. Accordingly, CMS should reverse this adjustment to all FY 2016, FY 2017, FY 2018, and FY 2019 payments, or make an equivalent prospective increase in payments to FY 2019 site neutral rate cases to account for this continuing underpayment.

QUALITY DATA REPORTING

Paperwork and Meaningful Measures Initiatives

In FY 2019 IPPS/LTCH PPS final rule CMS adopted a measure removal factor policy in the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Value-Based Purchasing (HVBP) Program. In the FY 2020 IPPS/LTCH PPS proposed rule CMS is proposing to adopt the same measure removal factors policies in the Hospital Readmissions Reduction Program (HRRP) and Hospital Acquired Condition (HAC) Reduction Program. Specifically, CMS proposed to adopt a set of eight quality measure removal factors for the HRRP and the HAC Reduction Program. The FAH strongly supports CMS's proposal to add the eight measure removal factors to the HRRP and HAC programs.

The FAH commends CMS for its proposed continued application of the Meaningful Measures framework to the HRRP and HAC program allowing the agency to prioritize and reduce the number of quality measures across the quality programs. This addresses our previously expressed concerns about the burden of managing many measures and the unnecessary duplication of measures across programs.

[8] MedPAC Comment Letter to CMS re: File Code CMS-1655-P at 16 (May 31, 2016). The letter states further: "MedPAC urges CMS to eliminate the proposed payment adjustment for discharges paid the site-neutral rate to account for outlier payments under this payment methodology. Given that the IPPS standard payment amount is already adjusted to account for HCO payments, CMS's proposal to reduce the site-neutral portion of the LTCH payment by a budget neutrality adjustment of 0.949 is duplicative and exaggerates the disparity in payment rates across provider settings. Given this duplication, CMS should not adjust the site-neutral rate further." *Id.* at 16-17 (emphasis added).

VIII. A. Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program requires hospitals to report measures without tying payment incentives or penalties to performance. Failure to report results in an annual market basket update reduction of one quarter. In addition, the IQR requires hospitals to report electronic clinical quality measures (eCQMs). Hospital IQR Program eCQM requirements align with Medicare and Medicaid Promoting Interoperability Program eCQM requirements.

Proposed Measure Additions

The CMS is proposing the addition of two new eCQMs related to opioids beginning with the FY 2021 reporting period and FY 2023 payment determination period. CMS is also proposing the addition of these measures to the Medicare and Medicaid Promoting Interoperability Program in keeping with alignment of eCQM reporting requirements.

The FAH commends CMS for its focus on opioid-related measures and in reducing preventable mortality related to opioid use. The FAH and its members actively seek to prevent unintentional opioid overdose fatalities and supports measures that address the opioid epidemic.

Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e)

This measure describes the proportion of adult patients (18 years and older) discharged from a hospital-based encounter with two or more opioid prescriptions or concurrent opioid and benzodiazepine prescriptions. The measure excludes patients with an active diagnosis of cancer or an order for palliative care.

The FAH supports the intent of this measure and appreciates that it is NQF endorsed but has serious concerns pertaining to the lack of alignment with current clinical guidelines, the feasibility and validity of this measure, and its potential unintended consequences. In particular, the FAH opposes mandatory reporting of this measure for the reasons stipulated.

Recently, the Centers for Disease Control and Prevention (CDC) published an article in the New England Journal of Medicine seeking to clarify the intent of the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016[9,10]. Specifically, the authors became aware of misapplication of the recommendations that could potentially lead to patient harms through abrupt tapering or discontinuation of opioids for current users of high opioid dosages and/or inclusion of patient populations for whom chronic use or higher dosages may be warranted. Based on the FAH's comparison of this eCQM against the CDC guideline recommendations, we believe that it is not currently supported by the recommendations.

The intent of the CDC guideline was to address the care provided by primary care providers for patients with chronic pain and many of the recommendations are not feasible or aligned with the evidence when applied to the inpatient setting. As specified, the measure is

[9] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

[10] Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. N Engl J Med. 2019 Apr 24. doi: 10.1056/NEJMp1904190. [Epub ahead of print]

likely to include patients who are already receiving one or both of these concurrent medications and for whom there is no strong evidence to support abrupt discontinuation of concurrent therapies; rather, tapering should be considered. Requiring that these drugs be discontinued in the acute care setting with the current average length of stay is not appropriate and has the potential to compromise patient safety and lead to patient harm.

In addition, the FAH believes that the measure would continue to have significant challenges with the feasibility and validity of the data even if the denominator was able to capture only new prescriptions and exclude patients who are already on these medications. Current documentation practices consider all medications that are administered during the inpatient stay as new prescriptions so hospitals would not be able to distinguish continuing versus new medications using EHR data. As a result, even if the denominator was modified, the data would not be a valid representation of the desired patient population. It is also possible that a patient already taking a benzodiazepine and admitted for a procedure or surgery receives a prescription for a low dose of an opioid for pain at discharge. This measure would classify this scenario as a quality failure when it should be considered appropriate clinical care. CMS must perform more detailed investigations into the potential scenarios where appropriate administration of concurrent medication may be warranted and better understand the feasibility and validity of the individual data elements.

This measure could result in providers not offering suitable pain solutions in the emergency department or inpatient setting, which is contrary to the goal of a positive patient care experience if these treatments are needed. In addition, the patient population must be further narrowed to capture the additional diagnoses where it is appropriate to use these medications (i.e., sickle cell crisis) as cancer and palliative care are not the only appropriate uses for these concurrent medications. This additional exclusion is supported in the NEJM article as they explicitly state that the recommendations do not apply to these populations.

Regarding the usefulness of the measure and its appropriateness to assess hospital performance, the FAH questions whether the limited focus of the measure on the inpatient setting provides a comprehensive picture of the quality of care to patients and whether it will drive improvements as intended. The FAH does not believe that focusing on prescription rates in the absence of understanding the root cause of the pain and pain management strategies will solve this public health concern; rather, examining pain and standardizing pain assessments and alternative therapies would be more beneficial.

Many hospitals are now focused on accurate documentation of opioid consumption at the time of admission to the hospital or emergency department due to the evidence that pain is often undertreated in the acute care setting. Reframing this measure to focus on adequate pain assessments and treatments would assist all of us in understanding the true problem rather than removing a downstream intervention. It would also be more broadly applicable to a broader set of patients and pain medications rather than the limited focus on opioids and benzodiazepines.

In summary, the FAH does not support holding the prescriber and hospital accountable for discontinuing medications safely in the limited amount of time during which a patient receives care in the inpatient setting, and believes that it is inconsistent with the current evidence and clinical recommendations.

Hospital Harm – Opioid Related Adverse Events eCQM

This measure calculates the percentage of acute care hospital adult patients (18 years and older), admitted through the ED or from observational status, experiencing an opioid-related adverse event during admission as indicated by the administration of naloxone. The numerator is composed of patients who received naloxone (a narcotic antagonist) either (1) outside the operating room (OR) after 24 hours from arrival to the hospital or; (2) during the first 24 hours after arrival to the hospital with evidence of hospital opioid administration prior to naloxone administration. The measure excludes patients receiving naloxone within 24 hours of arrival due to prior opioid overdose.

The FAH supports the intent of this measure to reduce preventable opioid-related adverse events but does not believe that the measure will achieve its intended effect and is likely to result in unintended consequences. The FAH does not support this eCQM for inclusion in the IQR Program.

The FAH believes that this measure could potentially result in under prescribing for pain control, disincentivize patients from showing up in the ED, or encourage more invasive procedures to bypass the use of naloxone in the event of an opioid-related adverse event. The FAH is also concerned that patients who already have prior long-term opioid prescriptions would experience these unintended consequences more acutely. These concerns align with those expressed by the MAP as they were concerned with the potential unintended consequences and recommended balancing measures on appropriate use of naloxone and adequate pain control.

The FAH also believes that the measure requires more precise specifications to ensure that the data elements accurately capture the intent of the measure. Specific recommendations to further improve the measure are:

- Using only the hospital location code for operating room alone to exclude administration of this drug during surgery is not sufficient. Administration of naloxone in the procedure room will not necessarily be captured and often the patients assigned a hospital location of an inpatient bed who are then sent for a procedure or operation do not have their location changed. Additional refinements must be made to the measure to ensure that all administrations of these drugs during a procedure or surgery are excluded.

- While the measure does not include any administration of naloxone during the first 24 hours of the inpatient stay if hospital staff did not administer an opioid, there is still the potential for situations where the hospital may not be aware of what medications were taken or administered prior to the patient's arrival and patients who require naloxone after opioid administration within the initial hours of admission may not represent inappropriate care. Because of this concern, the FAH recommends that any administration of naloxone regardless of whether an opioid is administered or not within the first twelve hours of arrival be excluded.

- The measure must also ensure that other appropriate uses of naloxone are excluded such as its administration for itching in patients with an epidural. Currently, the FAH believes that the specifications do not account for this potential scenario and CMS must examine what other appropriate uses are currently classified as quality failures when they are not.

These additional refinements must be completed to ensure that the measure yields results that are valid representations of the measure's intent and does not misrepresent the quality of care provided by a hospital.

Based on the recent submission of the measure to the NQF, the FAH is also concerned that testing occurred in only two electronic health record (EHR) systems and the performance scores across the five hospitals do not demonstrate sufficient variation. FAH strongly encourages CMS to assess the feasibility and validity of collecting the required data elements from additional EHRs. FAH is concerned that the complexity of the measure and, particularly the complexity of the numerator, may significantly impact an individual hospital's ability to successfully collect and report on each measure and testing in only two vendor systems does not adequately address this concern. Thorough assessments of each data element and the required calculations and logic must be vetted across more hospitals and vendor systems to truly understand whether this measure is ready for implementation. If the measure is not determined to be feasible and valid in the majority of vendor systems currently used, then it would be prudent for CMS to delay implementation until these gaps can be addressed.

In addition, FAH is concerned that the differences in scores may be minimal and may not yield reliable and valid representations of performance across the hospitals. Testing across the five hospitals provided scores ranging from 0.12% to 0.52%. Although eCQMs are not currently reported, the FAH questions whether these results would ensure that meaningful comparisons in the quality of care can be made and are useful to allow patients and families to distinguish higher quality of care and by hospitals for quality improvement.

Hybrid Hospital-Wide Readmission Measure (NQF #2879)

The CMS proposed the inclusion of the Hybrid Hospital-Wide Readmission (HWR) measure starting with the FY 2026 payment period as a replacement for the current claims-based HWR measure. The Hybrid HWR measure uses both claims data and a set of core clinical data elements and linking variables drawn from EHRs for patient risk adjustment and hospital service adjustment.

FAH believes CMS should delay proposing to include the Hybrid HWR into the Hospital IQR Program. First, hospitals are not yet able to provide fulsome comments on the measure and its implementation as a CQM in future years. A limited number of hospitals voluntarily participated in the measure in CY 2018, but CMS has not yet released this CY 2018 data, and hospitals have not yet had the opportunity to compare it to the traditional readmission measure. As such, the FAH believes hospitals are not able to provide comments on the measure at this time. Second, the FAH continues to have concerns about use of a hospital-wide all cause readmissions measure. The FAH does note, however, that the Hybrid HWR measure has improved risk adjustment – due to the inclusion of additional patient-level clinical factors – as compared to the existing HWR measure.

In addition, FAH continues to believe that the risk adjustment for this measure as well as many of the risk-adjusted outcome measures finalized in the IQR and other payment programs should address social risk factors. CMS must move beyond examining the impact of only a handful of variables such as dual eligibility status and the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index Score and this testing must consider new methods for testing rather than the current approach of "adding on" factors after the model is developed. New approaches would assist hospitals and others in understanding how the inclusion

of social risk factors could impact the model and provide additional information for groups examining this issue such as the National Quality Forum and Office of the Assistant Secretary for Planning and Evaluation. FAH urges CMS to continue to identify new approaches to testing and expand to new factors that are known to affect these rates and are beyond the hospital's control such as availability of healthcare providers and access to pharmacies and transportation as well as patient-level information such as education and language proficiency.

Proposed Measure Removals

Claims-based Hospital-Wide Readmission Measure

Should CMS adopt the Hybrid HWR measure, the FAH supports the removal of the Claims-based HWR measure contingent on the adoption of the Hybrid HWR measure. The FAH requests that CMS carefully examine the correct timing of the removal of the claims-based HWR measure to ensure that reporting of these data are continuous and not impacted by any unplanned delays as the Hybrid HWR measure is incorporated. In addition, we suggest that CMS work with hospitals during the voluntary reporting periods to ensure that any issues are identified and addressed before the measure becomes mandatory.

Potential Future Hospital IQR Program Measures

Hospital Harm – Severe Hypoglycemia eCQM

This measure assesses the proportion of patients who experience a severe hypoglycemic event within 24 hours of the administration of an antihyperglycemic agent.

FAH recognizes the need to address this important patient safety events but cautions CMS on proposing any of the hospital harm eCQMs until the conditions outlined by the Measures Application Partnership (MAP) are addressed and additional testing is completed. Specifically, the MAP expressed concerns including the need to assess whether this measure leads to unintended consequences and pairing this eCQM with a balancing measure on hyperglycemia. It is FAH's understanding that an eCQM on hyperglycemia is in development and we recommend that CMS not move forward with this measure until the development of this balancing measure is complete.

Based on the recent submission to the NQF, FAH was concerned that the eCQM was only tested in two EHRs and the performance scores across the six hospitals do not demonstrate sufficient variation. FAH strongly encourages CMS to assess the feasibility and validity of collecting the required data elements from additional EHRs. FAH is concerned that the complexity of the measure and, particularly the complexity of the numerator, may significantly impact an individual hospital's ability to successfully collect and report on each measure and testing in only two vendor systems does not adequately address this concern. Thorough assessments of each data element and the required calculations and logic must be vetted across more hospitals and vendor systems to truly understand whether this measure is ready for implementation. If the measure is not determined to be feasible and valid in the majority of vendor systems currently used, then it would be prudent for CMS to delay implementation until these gaps can be addressed.

In addition, FAH is concerned that the differences in scores may be minimal and may not yield reliable and valid representations of performance across the hospitals should eCQM data be

publicly reported in the future. Testing across the six hospitals provided scores ranging from 1.05% to 3.56%. FAH questions whether these results would ensure that comparisons in the quality of care can be made and are useful to allow patients and families to distinguish higher quality of care and by hospitals for quality improvement, in the event that they begin to be publicly reported.

Hospital Harm – Pressure Injury eCQM

This measure assesses the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization.

FAH supports the intent of this measure but believes that additional work must be completed prior to its proposal for the IQR Program since the MAP identified several areas of concern for which the current iteration of the measure does not address based on the recent submission to the NQF. Specifically, the MAP suggested that additional exclusions should be considered for those patients undergoing treatments for which it may not be appropriate to receive pressure injury reducing interventions such as extracorporeal membrane oxygenation (ECMO), which has not been addressed. This group also expressed concern over the potential reliability of several of the data elements required including present on admission and pressure injury staging. Each of these issues will impact the validity of the measure score and must be addressed prior to implementation.

On review of the data element validity testing submitted to NQF, the results confirm some of the MAP's concerns regarding the ability to accurately and consistently capture pressure injury staging within the EHR. Because testing occurred in only three EHRs with one demonstrating that this information was more likely to be found in free text clinical notes and not a discrete field, FAH strongly encourages CMS to assess the feasibility and validity of collecting the required data elements from additional vendor systems. This measure should not be proposed implemented prior to answering the question on the degree to which the lack of discrete data may impact an individual hospital's ability to successfully collect and report on each measure and the extent to which it may misrepresent performance. Thorough assessments of each data element and the required calculations and logic must be vetted across more hospitals and vendor systems to truly understand whether this measure is ready for implementation. If the measure is not determined to be feasible and valid in the majority of vendor systems currently used, then it would be prudent for CMS to delay proposing its inclusion in the IQR Program until these gaps can be addressed.

In addition, FAH is concerned that the differences in scores may be minimal and may not yield reliable and valid representations of performance across the hospitals should public reporting on eCQMs begin in the future. Testing across the twenty-four hospitals provided scores ranging from 0.00% to 1.46%. FAH questions whether these results would ensure that comparisons in the quality of care can be made and are useful to allow patients and families to distinguish higher quality of care and by hospitals for quality improvement.

Cesarean Birth PC-02 eCQM (NQF #0471e)

This measure assesses the rate of nulliparous women with a singleton baby in the vertex position delivered by cesarean birth.

The FAH supports the intent of the measure to decrease the rate of cesarean births but believes that examining the quality of care delivered to mothers and babies should be more holistic and balanced (e.g., ensure the delivery of healthy term newborns). Specifically, FAH does not believe that inclusion of a limited number of obstetric measures in the Inpatient Quality Reporting Program or Medicare and Medicaid EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals (PC-1, Elective Delivery and Cesarean Birth) will provide a comprehensive picture of the desired outcomes. Neither measure can achieve optimal performance rates (i.e., 100% for Elective Delivery, 0% for Cesarean Birth) and CMS must ensure that their individual use does not create unintended consequences.

FAH does not support future proposal of this measure in light of the concerns expressed during the MAP meeting regarding the need for additional exclusions and refinements to the denominator to capture high-risk conditions and risk adjustment. In addition, during this review, it became clear that the NQF Scientific Methods Panel did not believe that this eCQM met the minimum requirements for reliability and validity due to the small sample size used for testing and lack of risk adjustment. To FAH's knowledge, these issues have not been addressed and measures that have not successfully achieved NQF endorsement should not be considered for implementation.

Potential Future Hospital IQR Program Measures

The CMS proposes that beginning with the FY 2022 reporting period/FY 2024 payment determination period hospitals report one self-selected calendar quarter of data for the proposed Safe Use of Opioids Concurrent Prescribing eCQM plus three additional self-selected eCQMs.

The FAH does not support the mandatory reporting of Safe Use of Opioids Concurrent Prescribing eCQM. The FAH further cautions that adoption of new eCQMs takes considerable time and effort and hospitals often have to wait on vendors to configure the specifications followed by very short time frames on the facility side to implement effectively and validate that data is getting captured accurately. To this end specifications for any new measure need to be made available as early as possible.

VIII. C. LTCH Quality Reporting Program (LTCH QRP)

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) reduces the annual update to the LTCH PPS standard Federal rate for discharges by 2 percentage points during a fiscal year if the LTCH does not comply with the LTCH QRP requirements specified for that fiscal year. The LTCH QRP currently has 15 measures.

LTCH QRP Quality Measure Proposals Beginning with the FY 2022 LTCH QRP

CMS is proposing the adoption of two process measures:

- Transfer of Health Information to the Provider - Post-Acute Care (PAC)
- Transfer of Health Information to the Patient - Post-Acute Care (PAC)

The FAH supports adoption of the process measures once they have been endorsed by the National Quality Forum (NQF) as per the conditional support issued by the MAP Coordinating Committee. The FAH would like to see more information regarding CMS's plan to validate measure accuracy across different PAC settings.

LTCH QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

CMS is seeking input on a number of measures, standardized patient assessment data elements SPADEs) and concepts under consideration.

The FAH does not support adoption of all 35 proposed SPADEs and cautions CMS that they are underestimating the burden behind data collection related to these measures and SPADEs and suggests that only a narrow subset be added. In particular, the following SPADEs would pose substantial burden to frontline clinicians that goes contrary to CMS's Patients over Paperwork initiative: Brief Interview for Mental Status, Health Literacy, Patient Health Questionnaire-2 to 9, and the interview for Pain Interference with sleep, therapy , and day-to-day activities. In addition, the FAH is concerned that the Confusion Assessment Method ("CAM") SPADE is not appropriate for the LTCH setting due to its lack of sensitivity in detecting improvements in the cognitive function of patients. ***Finally, The FAH requests that CMS lower the LTCH QRP compliance threshold beginning with the FY 2022 LTCH QRP payment determination due to the significant burden associated with the addition of 35 new SPADEs to the LTCH CARE Data Set.***

Proposed Form, Manner, and Timing of Data Submission Under the LTCH QRP

The FAH supports CMS's proposal to move the implementation date for new version of the LTCH CARE Data Set from April to October.

XIII.D. Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

The FAH continues to believe that health information technology (HIT) holds enormous potential to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates CMS's efforts to further the exchange and use of information and offers the below comments in response proposed changes to the Medicare and Medicaid Promoting Interoperability Programs (PIPs).

1.b. Goals of Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

The FAH supports the goals of the proposed changes to the PIPs outlined in the Proposed Rule, including providing stability, reducing administrative burden, improving patient access to their medical records, and continued use of the 2015 Edition certified electronic health record technology (CEHRT). In response to the recent ONC interoperability and information blocking Proposed Rule, the FAH commented that the proposed changes to the 2015 Edition necessitates a new name to avoid stakeholder confusion. Should ONC finalize the proposed 2015 Edition changes and adopt a new moniker, the FAH notes that CMS should change references to the 2015 Edition in the Medicare and Medicaid PIP rules.

2. Electronic Health Record (EHR) Reporting Period

The FAH supports CMS's proposed change to the CY19 reporting period to provide eligible hospitals all of CY19 to complete their 90-day EHR reporting period for the FY 2020 payment adjustment year. The FAH also supports the proposed EHR reporting period of a minimum of any continuous 90-day period in CY21 for both new and returning eligible hospitals and Critical Access Hospitals (CAHs). The FAH agrees with CMS that this proposal provides stability as eligible hospitals and CAHs implement the changes finalized in the FY19 IPPS Final Rule.

CMS is also proposing that, beginning with the CY20 reporting period, the numerators and denominators of measures (other than the Security Risk Analysis measure) would only increment based on actions that have occurred during the EHR reporting period selected by the eligible hospital or CAH.[11] The FAH does not support this proposed change and instead recommends that CMS maintain the current policy of permitting numerators and denominators of measures to accrue as long as the action occurred within the CY (i.e., an action during the CY but outside of the hospital's selected reporting period would accrue toward the measure). The proposed change would require hospitals and their HIT vendors to completely rebuild their reporting processes, which will take significant time for an unclear goal.

3. Proposed Changes to Measures Under the Electronic Prescribing Objective

b. Query of a Prescription Drug Monitoring Program (PDMP) Measure

The FAH appreciates CMS's recognition that "PDMPs are still maturing in their development and use," that "there is no uniform way of accessing PDMP data across states, as data platforms differ by state," and that providers must often go outside their EHR to separately access the state PDMPs.[12] As such, the FAH supports CMS's proposal to remove the numerator and denominator for the Query of PDMP measure and replace it with a "yes/no" response for the CY19 and CY20 EHR reporting periods, with a "yes" response meaning that the eligible hospital or CAH used data from the CEHRT to query a PDMP for at least one Schedule II opioid electronically prescribed using CEHRT. The FAH also supports CMS's proposal to make this measure option in CY20 as well and appreciates CMS's clarification that a "yes" response for this measure would earn the full five bonus points for CY19 and CY20.

In response to CMS's request for comment on future timing for an EHR-PDMP integration measure, the FAH believes that CMS should not implement such a measure until the state PDMPs mature and platform variation across states is mitigated. There will also need to be sufficient time for HIT vendors to design and build the EHR-PDMP integration and then time for hospitals and CAHs to implement the systems, including testing and staff training. Implementing such a measure too quickly would lead to similar confusion and workarounds as occurred with the public health reporting requirements where some states are simply unable to perform the bidirectional information exchange.

[11] The FAH notes an error on page 19555 of the Proposed Regulation. The title of the subsection on page 19555 of the Proposed Rule is "b. Promoting Interoperability Measures: Actions Much Occur Within the EHR Reporting Period." As there is already a "2.b". on page 19554, the FAH believes this subsection should instead be labeled as subsection "c."

[12] 84 Fed. Reg. 19556 (May 3, 2019).

c. Verify Opioid Treatment Agreement Measure

The FAH echoes the concerns noted by CMS in the Proposed Rule with regard to the Verify Opioid Treatment Agreement measure and strongly supports CMS's proposal to remove the measure beginning with the CY20 reporting period. The FAH believes the concerns with this measure are insurmountable and that it is not an appropriate measure for inpatient hospitals. As such, the FAH would not support implementation of this measure in future rulemaking.

4. Health Information Exchange Objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information

CMS is proposing to clarify that, for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the "electronic summary of care record must be received using CEHRT and that clinical information reconciliation for medication, medication allergy, and current problem list must be conducted using CEHRT."[13] The FAH supports this technical correction and believe it more accurately reflects how eligible hospitals and CAHs have interpreted and implemented the measure requirements.

5. Proposed Changes to the Scoring Methodology for Eligible Hospitals and CAHs Attesting to CMS Under the Medicare Promoting Interoperability Program for an EHR Reporting Period in CY 2020

For the CY20 reporting period, CMS is proposing to: remove the Verify Opioid Treatment Agreement measure; keep the Query of PDMP measure optional and eligible for five bonus points; and change the e-Prescribing measure to a maximum of ten points. The FAH strongly supports these changes and, as noted above, appreciates CMS's recognition of the concerns associated with these two opioid-related measures.

6. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the Medicare and Medicaid Promoting Interoperability Programs

b. Proposed Additional CQMs for Reporting Periods Beginning With CY 2021

CMS is proposing the addition of two new eCQMs related to opioids beginning with the FY21 reporting period and FY23 payment determination period. CMS is also proposing the addition of these measures to the PIP in keeping with alignment of eCQM reporting requirements.

The FAH supports CMS's continuing alignment of the PIP with the Hospital IQR program. The FAH also commends CMS for its focus on opioid-related measures and in reducing preventable mortality related to opioid use. For specific comments on the two proposed opioid measures, please see Section VIII.A. Hospital Inpatient Quality Reporting (IQR) Program of this comment letter.

c. RFI Regarding Potential Adoption of the Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and EHR data (Hybrid HWR Measure) for Reporting Periods Beginning with CY 2023

[13] *Id.* at 19559.

The FAH urges CMS to hold off on proposing the Hybrid HWR measure as eligible hospitals and CAHs are not yet able to provide fulsome comments on the measure and its implementation as a CQM in future years. For more detailed comments, please see Section VIII.A. Hospital Inpatient Quality Reporting (IQR) Program of this comment letter.

d. Proposed CQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2020, 2021, and 2022

The FAH supports CMS's proposal to continue the current reporting criteria for the CY20 and CY21 reporting periods of electronically reporting four self-selected CQMs for one, self-selected quarter.

For the CY22 reporting period, CMS is proposing that electronically reporting eligible hospitals and CAHs would report three self-selected CQMs plus the proposed Safe Use of Opioids – Concurrent Prescribing CQM for one, self-selected calendar quarter. As the Safe Use of Opioids measure is newly proposed for CY20, the FAH believes that more time is needed before making it a required CQM. Given the implementation challenges that often arise with new measures and the lag in data collection and reporting, the FAH believes that the measure should not be required until at least CY23.

7. Future Direction of the Promoting Interoperability Program

a. RFI on Potential for Opioid Measures for Future Inclusion in the PIP

CMS seeks comment on possible future measures relevant to clinical priorities related to addressing opioid use disorder prevention and treatment. The FAH believes that CMS must implement a broader focus on pain management to provide a more comprehensive picture of the quality of care to patients and whether a set of measures on this broader topic could drive improvements as intended. The FAH does not believe that narrowly focused measures on opioids in the absence of understanding the root cause of the pain and pain management strategies will solve this public health concern; rather, examining pain and standardizing pain assessments and alternative therapies in addition to understanding current opioid prescribing practices would prove more beneficial to hospitals and the patients they serve.

The FAH also recommends that CMS explore the development of measures that better define the processes and outcomes that hospitals can improve, such as:

- Naloxone education and referral at discharge;
- Use of high-risk medications in the elderly, such as initial doses of hydromorphone and use of morphine in patients with renal failure;
- Elimination or reduction of Demerol administration and other drugs that have an increased potential for addiction; and
- Education on and appropriate wasting of opioids.

The FAH also strongly urges CMS to complete more in-depth and broad assessments of feasibility to collect many of the individual data elements required for eCQMs in the hospital setting. The FAH identified several areas in our comments that are unique to the inpatient setting and directly impact a hospital's ability to collect the required data to ensure valid assessments of the quality of care delivered. These challenges include but are not limited to the:

- Documentation practices and clinical workflows in EHRs that differ in the inpatient setting such as the capture of only new prescriptions rather than continuing prescriptions;
- Lack of integration of PDMPs with EHRs, the limited ability to allow broad access to these data due to privacy concerns, and the simplicity of these systems that do not allow tracking of what specific information was accessed by health care professionals.

These challenges must be balanced with the changes to EHRs, documentation practices, and clinical workflows that would be required. Prioritization must be given to those areas that can lead to improvements in care delivery and the quality of care provided to our patients. Measures that lead to modifications that do not directly result in these improvements and are not based solidly in evidence should not be considered.

b. RFI on NQF and CDC Opioid Quality Measures

The FAH does not support the potential inclusion of all three of the NQF measures in the PIP due to misalignment of the measures with current evidence and the inapplicability of a measure designed to assess health plan performance to a hospital inpatient setting using EHRs. Specific concerns with each measure can be found below.

The FAH supports exploring the development of some of the Centers for Disease Control and Quality (CDC) Quality Improvement (QI) opioid measures for potential inclusion in the PIP. Specific feedback and recommendations on these measures can be found below.

<u>Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)</u>

The FAH has significant concerns with potential implementation of this measure within the PIP and does not support its inclusion in future years. The FAH does not believe that the measure as defined is aligned with the current evidence nor do we believe that a measure developed to assess health plan performance using administrative claims data can feasibly be captured through EHRs in the inpatient setting.

In May, the CDC published an article in the New England Journal of Medicine seeking to clarify the intent of the CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016.[14] Specifically, the authors became aware of misapplication of the recommendations that could potentially lead to patient harms through abrupt tapering or discontinuation of opioids for current users of high opioid dosages and/or inclusion of patient populations for whom chronic use or higher dosages may be warranted. Based on the FAH's comparison of this measure against the CDC guideline recommendations, we believe that it is not currently supported by the recommendations.

The intent of the CDC guideline was to address the care provided by primary care providers for patients with chronic pain, and many of the recommendations are not applicable or feasible in the inpatient setting. The FAH believes that the measure does not sufficiently define the patient population since it does not exclude current opioid users, those patients receiving palliative care, or those who have a diagnosis of sickle cell disease. In addition, current

[14] Dowell D, Haegerich TM, Chou R. *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*. MMWR Recomm Rep 2016;65(No. RR-1):1–49. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. *See also* Dowell D, Haegerich T, Chou R. *No shortcuts to safer opioid prescribing*. N Engl J Med. 2019 Apr 24. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp1904190.

documentation practices in the EHRs capture all medications prescribed within the hospitalization as new prescriptions so it would be extremely difficult, if not impossible, to identify continuing versus new medications.

Even if the measure is modified to better align with the current evidence, this measure was developed and tested at the health plan level, and the developers have not demonstrated how well any of these three NQF measures perform within a hospital. Hospitals do not have access to prescription claims data from CMS, which the FAH believes would be required to begin to capture the intent of this measure. If the measure was re-specified to be derived data from EHRs, only prescribing rates would be captured, and FAH does not believe that it would yield reliable and valid representations of a hospital's performance.

The FAH also questions how hospitals can and should be held accountable for measures that extend well past the typical length of stay. This measure determines the extent to which patients are receiving high dosages of opioids for 90 consecutive days or longer. Asking hospitals to identify ways to capture and document this information for a measure that is better suited to measurement at the health plan level and using administrative claims is impractical.

The FAH does not believe that this measure is evidence based nor would it produce reliable and valid information that would be useful for accountability or quality improvement uses by hospitals, patients or the public. The FAH does not support further consideration of this measure for future implementation in this program.

Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950)

The FAH has significant concerns with potential implementation of this measure within the PIP and does not support its inclusion in future years for reasons similar to those outlined above regarding NQF #2940. The FAH does not believe that the measure as defined is consistent with the guideline recommendations nor do we believe that a measure developed to assess health plan performance using administrative claims data can feasibly be captured through EHRs in the inpatient setting.

Because the denominators for NQF #2940 and this measure are the same, our comments regarding the lack of alignment with the CDC's guideline recommendations also apply here. The denominator must be further refined to exclude current opioid users, those patients receiving palliative care, or those who have a diagnosis of sickle cell disease.

The FAH was also unable to determine how a measure that examines whether patients received prescriptions for opioids from four or more prescribers and four or more pharmacies could be easily obtained by hospitals and by using EHR data. While PDMPs could serve as a potential resource for this measure, hospitals continue to face challenges in their use given the varied requirements across states. For example, access to the PDMP is often limited due to concerns with patient privacy so not all health professionals and staff are able to see the individual patient information nor are these data integrated into EHRs.

The FAH does not believe that this measure, if re-specified to assess hospital performance, would yield reliable and valid results. The FAH does not support further consideration of this measure for future implementation in this program.

Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951)

The FAH does not support this measure's inclusion in the PIP in future years. Due to our detailed comments and concerns outline above regarding the Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940) and Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950) measures, the FAH does not believe that this measure should be considered in future proposed rules.

CDC QI Measures

The FAH supports exploring the development and specification of some of the CDC QI opioid measures for potential consideration in the PIP. Not every measure is appropriate or feasible for implementation to the inpatient setting, and the FAH believes that some measures would require modification. Specific suggestions and comments include:

Measure #1: The FAH supports this measure conceptually but recommends that patients prescribed opioids within the first twelve hours of admission be excluded from this measure.

Measure #2: The FAH supports this measure conceptually but believes that it cannot be measured through EHRs at this time. For example, PDMPs are currently separate systems from EHRs, and the data is not yet integrated. In addition, while PDMPs can identify whether an individual signed into the system, identifying what information was accessed is not captured, and hospitals would be unable to determine this information for each individual patient. These challenges with data collection and accuracy would need to be addressed prior to further development of this measure as an eCQM.

Measure #5: This measure could potentially be feasible and useful, but the FAH foresees challenges with identifying the correct denominator of patients with a new prescription. Determining new prescriptions versus continuing prescriptions during the hospitalization must be addressed prior to further development. Medications would also need to be electronically captured through e-prescribing.

Measure #15: The FAH believes that development of a measure targeting Naloxone counseling and education at the time of discharge might be worthwhile and could be feasible to implement.

Measures #3, 4, 6-14: The FAH does not believe that these measures should be considered for the PIP as they are more suited to the outpatient setting and not appropriate for inpatient hospital measurement.

c. RFI on a Metric to Improve Efficiency of Providers Within EHRs

CMS is seeking comments on how implementation of more efficient workflows can be effectively measured as part of the PIP, as well as to how to measure and incentivize efficiency as it related to the use of CEHRT and the furthering of interoperability. The FAH believes this could be valuable but is unclear how such efficiencies would be measured (e.g., number of clicks, time on a screen, time to complete an encounter, time to complete medication reconciliation) and whether CMS is interested in measuring health care providers or the HIT vendors. While health care providers can control some aspects of HIT systems (e.g.,

customization of user interfaces and staff training), most aspects of the systems, particularly the technical functionality, is entirely in the purview and control of the HIT vendors. Should CMS continue to explore such measures, the FAH urges CMS to focus on measurement in such a way that spurs efficiencies rather than simply adding another reporting obligation, such as through bonus points as opposed to a mandatory measure.

d. RFI on Including Medicare Promoting Interoperability Program Data on the Hospital Compare Website

CMS seeks comment on potentially posting the performance rate for some or all of the PIP measures on the *Hospital Compare* website in future years. The FAH questions the utility of posting the performance rates for individual measures (or some sort of aggregate performance rate) on *Hospital Compare*. Specifically, the FHA believes such information is not useful to – and is actually confusing for – patients and their families. Additionally, the previously finalized PIP scoring methodology allows eligible hospitals and CAHs to focus on a subset of measures and objectives within the PIP, while not focusing as intently on others. Thus, public reporting of individual measures could make an eligible hospital or CAH look as though it is a low performer when it is in fact achieving meaningful use of CEHRT and advancing interoperability.

e. RFI on the Provider to Patient Exchange Objective

Immediate Access

As CMS notes in the Proposed Rule, the current Provide Patients Electronic Access to Their Health Information measure requires that the eligible hospital or CAH provide patients "timely access" to view, download, and transmit their health information and that it must be available to the patient within 36 hours of its availability to the facility.[15] In this RFI, CMS seeks comment on whether eligible hospitals and CAHs should make patient health information available immediately through the open, standards-based application programming interface (API), not later than one business day after it is available to the eligible hospital or CAH.[16]

Should CMS move forward in future rulemaking with updating this measure to account for the implementation of open, standards-based APIs, the FAH urges CMS to maintain the current timeframe of 36 hours to make the information available to patients. The data being available to the eligible hospital or CAH in their EHR is not necessarily indicative of that information being immediately available via the API, as some eligible hospitals and CAHs perform behind-the-scenes work to aggregate a patient's data from all of health system's facilities to ensure the patient is receiving accurate, updated, combined data and a better user experience. In addition, the FAH urges CMS to ensure that any changes to this measure align with any relevant policies (e.g., information blocking) from the recent ONC interoperability and information blocking Proposed Rule that are eventually finalized.[17]

[15] 84 Fed. Reg. 19567 (May 3, 2019).

[16] *Id.*

[17] 84 Fed. Reg. 7590 (March 4, 2019). For example, the proposed regulation at §170.315(b)(10)(A) in the ONC Proposed Rule states that a single patient EHI export from certified technology must "Enable a user to timely create an export file(s) with all of a single patient's electronic health information the health IT produces and electronically manages on that patient."

Persistent Access

CMS is seeking comment on whether to revise the existing Provide Patients Electronic Access to Their Health Information measure to align with the technical requirement proposal for persistent access to APIs in the ONC Proposed Rule. Specifically, that proposal would permit third-party applications persistent access to an API via an authorization token that would last for three months, meaning the patient would not need to reauthorize the third-party application he is using to access his information or reauthenticate his identity in that three-month period.

The FAH would not support aligning the PIP Provide Patients Electronic Access to Their Health Information measure with this proposed ONC policy, as the FAH believes the proposed ONC policy raises privacy and security concerns and should not be finalized. The FAH instead recommends requiring reauthentication each time information is sought via the API. Reauthentication at each use is in line with industry standards for accessing other applications containing sensitive information, such as banking or credit card applications, and would not be unduly burdensome on the consumer.

Should ONC finalize its certification criteria proposal to require a FHIR-based API, CMS is also seeking comment on providing bonus points under the PIP for eligible hospitals and CAHs that adopt a certified FHIR-based API prior to the compliance data set by ONC. Should ONC finalize its proposal, the FAH would support bonus points under the PIP for early adopters of the FHIR-based API.

Available Data – EHI Export

CMS is seeking comment on an alternative measure under the Provider to Patient Exchange objective requiring eligible hospitals and CAHs to use "technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR."[18]

The FAH would have serious concerns with such an alternative measure. First, the EHI export criteria was proposed in the recent ONC interoperability and information blocking Proposed Rule and have not yet been finalized. These criteria are new, untested, and will not be implemented for a few years, and thus it is difficult for eligible hospitals and CAHs to provide CMS with fully informed feedback on how such a measure might operate under the PIP. There are also significant outstanding questions and concerns regarding ONC's EHI export criteria proposal. For example, in the FAH's response to the ONC Proposed Rule, the FAH requested clarity regarding ONC's intent in proposing to require that the data be exported in "computable" format and noted that some data for export may be "digital" but not "computational" in nature (e.g., a PDF document). In another example, the FAH comments in response to the ONC Proposed Rule noted that data exported to a single patient for use in his own care differs substantially from the data required by a provider about their patient population to facilitate full migration during an IT system transition (the other proposed EHI export criteria function). As such, the FAH recommended that ONC allow for variations in functionality appropriate to the two use cases (i.e., individual patient access; health care provider IT system transition) when assessing HIT modules submitted for certification to the EHI export criterion.

[18] *Id.*

Second, as the EHI export criteria lack standardization and maturity, they cannot currently provide electronic access to all information contained in an EHR in a format that is understandable to patients and their families. Providing the information in a non-standardized format – as it would be implemented under the ONC Proposed Rule – would have no marginal benefit for the patient over providing the information via a paper copy.

Third, the FAH comments in response to the ONC Proposed Rule noted that, under HIPAA, a single patient user is entitled to access his designated record set. As such, the FAH recommended that the EHI export be limited to EHI that is part of the designated record set, which may not be all information contained within an EHR.

Given the concerns raised above, the FAH cautions CMS against developing such an alternative measure – at least until these issues are addressed. Should CMS eventually move forward with such a measure under the PIP, the FAH recommends that the measure be an attestation (i.e., "yes/no") measure, with a "yes" response signaling that your EHR has the EHI export functionality.

Available Data – Information Exchange Across the Care Continuum

CMS is also seeking comment on a possible future HIT activity that encourages health information exchange across the care continuum, including exchange with post-acute care providers, behavioral health providers, and community-based service providers.[19]

As FAH noted in response to the recent CMS patient access Proposed Rule, the FAH appreciates CMS's interest in improving health information exchange across the health care continuum to improve the quality and efficiency of patient care and believes the best way to achieve that goal is through the use of "incentives" – such as financial support and/or regulatory relief – rather than "sticks" – such as Conditions of Participation (CoPs) or complex regulatory requirements. For example, the FAH comments encouraged CMS to explore whether health care providers that do not participate in the Medicare or Medicaid EHR Incentive Programs could receive support through CMMI, such as providing the fees for those providers to join health information exchanges (HIEs), health information networks (HINs), or prescription drug information exchanges; and/or increasing reimbursements for those providers that engage in information exchange.

The Draft TEFCA 2.0 also offers the potential for enhanced interoperability through voluntary engagement with Qualified HINs. For example, a hospital participating in TEFCA could be deemed to meet the Health Information Exchange objective. While the TEFCA is further revised and implemented, CMS could provide full credit for the Health Information Exchange objective to providers who participate in a HIN. As noted in the FAH comments in response to the Draft TEFCA 2.0, the FAH urges CMS and ONC to align the TEFCA, the information blocking requirements, and the PIP to the fullest extent possible to encourage greater electronic data exchange and promote interoperability.

Lastly, to encourage exchange of information between acute care and post-acute care providers, the FAH comment letter in response to the recent CMS patient access Proposed Rule recommended incorporating some post-acute care data elements into the USDCI. This

[19] *Id.* at 19568.

incorporation of elements over time would allow acute care providers to collect and exchange some post-acute care data elements consistently across providers.

Patient Matching

The FAH appreciates CMS's and ONC's commitment to improving patient matching, including facilitating private sector efforts in the absences of a unique patient identifier (UPI). The FAH provided comments on patient matching in response to the recent CMS patient access Proposed Rule and refers the Agency to that letter for additional details on the FAH's recommendations.[20]

f. RFI on Integration of Patient-Generated Health Data Into EHRs Using CEHRT

CMS is seeking comment on ways the PIP could adopt new elements related to patient-generated health data (PGHD) that are clearly defined uses of HIT; lined to positive outcomes; and advance the capture, sharing, and use of PGHD.[21] The FAH notes that there are limited use cases for the capture of most PGHD (e.g., wearables) in the inpatient hospital setting. The use cases most relevant to inpatient hospitals and CAHs are: patients sharing advance directive information with the facility and enabling patients to complete their medical history questionnaire and other related materials prior to admission – or while patients are in the waiting room prior to their visit.

PROVIDER REIMBURSEMENT REVIEW BOARD

XI. Provider Reimbursement Review Board (PRRB) Appeals

Perhaps as a result of the litigation concerning the backlog in the Medicare Part A and B claims appeal process, and looking to get ahead of similar criticism concerning the Part A cost report appeals process, in Section XI of the FFY 2020 IPPS Proposed Rule, CMS noted that, between 2015 and 2017, "Medicare Part A providers filed cost report appeals at a higher rate than were resolved" in that on average "3,000 appeals were filed per year and approximately 2,200 were resolved." *See* 84 Fed. Reg. 19579. The Proposed Rule noted that the PRRB's "inventory is now over 10,000 (including approximately 5,000 group appeals)."

The Proposed Rule noted that CMS had "identified certain action initiatives that could be implemented with the goal to: Decrease the number of appeals submitted; decrease the number of appeals in inventory; reduce the time to resolution; and increase customer satisfaction." The "action initiatives" identified in the Proposed Rule were:

1. Develop standard formats and more structured data for submitting cost reports and supplemental and supporting documentation.
2. Create more clear standards for documentation to be used in auditing of cost reports.
3. Enhance the Medicare Cost Report Electronic Filing (MCReF) portal by creating more automation for letter notifications, increasing provider transparency during the cost report

[20] Federation of American Hospitals comment letter Re: Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-facilitated Exchanges and Health Care Providers (June 3, 2019), available at: https://www.fah.org/fah-ee2-uploads/website/documents/CMS_Proposed_Rule_-_FAH_Letter_-_FINAL.pdf.

[21] 84 Fed. Reg. 19569 (May 3, 2019).

reconciliation process, and improving the ability for providers to see where they are in the process.

4. Explore opportunities to improve the process for claiming DSH Medicaid eligible days as part of the annual Medicare cost report submission and settlement process.
5. Utilize artificial intelligence (AI) design risk protocols based on historical audit outcomes and empirical data to drive the audit and desk review processes.
6. Triage the current appeals inventory and expand the provider's utilization of PRRB rules 46 and 47.2.3 (that is, resolve appeal issues through the cost report reopening process).

However, CMS did not seek comments on all of these initiatives. Rather, CMS cross-referenced Section IV.F.5. of the Proposed Rule (84 Fed. Reg. 19422-23), where CMS stated that it was "requesting public comments on PRRB appeals related to a hospital's Medicaid fraction in the DSH payment adjustment calculation." Thus, CMS is explicitly seeking comments only as to action initiative 4. But, as explained below, CMS also seems open to comments on action initiative 6.

Section IV.F.5. addresses the "backlog" of PRRB appeals, focusing on the Medicaid-eligible "timing" days issue, which arises because the list of Medicaid-eligible days available at the time a hospital files Medicare cost report is generally incomplete because States typically need a few years to generate a complete list of their Medicaid-eligible individuals, including those whose eligibility is established years later, after the successful appeal of an initial denial of Medicaid eligibility. CMS's focus on this issue is somewhat unexpected because, with the implementation of UC-DSH, this empirical DSH issue would seem to have diminished financial importance. But, perhaps, that is why CMS wants <u>finally</u> to figure out a low-cost, administratively simple way to resolve this issue.

To that end, CMS makes two proposals. One would allow hospitals to request reopening on this issue within 3 years of cost report settlement and require MACs to grant that reopening request. This generally seems like a good idea, but could end up being unhelpful for hospitals if the practical result is to swap an appeal backlog for a reopening backlog. The second is a "one-time option" to allow hospitals to resubmit their cost reports with updated Medicaid-eligible days information. However, CMS does not explain how this option is different from (and superior to) seeking reopening. CMS seeks comments on these options and "any alternative approaches [] that could help reduce the number of DSH-related appeals and inform [CMS's] future rulemaking efforts. Our comments are set forth below.

We support CMS's focus on efforts to reduce the backlog of appeals at the Provider Reimbursement Review Board (PRRB), as part of CMS's ongoing efforts to reduce regulatory burdens on providers. And we look forward to learning more about the "action initiatives" identified in Section XI of the Proposed Rule (84 Fed. Reg. 19579), for which CMS did not explicitly request comments. We urge CMS to identify and explain all current initiatives being considered internally relating to expediting resolution of PRRB appeals and solicit public comments on them, while also asking stakeholders for additional suggestions about how to reduce the regulatory burden associated with pursuing a PRRB appeal.

Section XI notes that Section IV.F.5. of the Proposed Rule (84 Fed. Reg. 19422-23) is "requesting public comments on PRRB appeals related to a hospital's Medicaid fraction in the DSH payment adjustment calculation." Section IV.F.5. addresses the "backlog" of PRRB appeals by focusing on the Medicaid-eligible "timing" days issue, which arises because the list of Medicaid-eligible days available at the time a hospital files Medicare cost report is generally

incomplete because States typically need a few years to generate a complete list of their Medicaid-eligible individuals, including those whose eligibility is established years later, after the successful appeal of an initial denial of Medicaid eligibility. CMS's focus on this issue is somewhat unexpected because, with the implementation of UC-DSH, this empirical DSH issue has significantly less financial impact after the start of Federal fiscal year 2014. But, perhaps, that is why CMS wants to figure out a low-cost, administratively simple way to address this issue, which may be included in a high number of appeals and which the Federation supports.

CMS makes two proposals to eliminate appeals on the Medicaid-eligible "timing" days issue. The first proposal would allow hospitals to request reopening on this issue and "set a realistic period during which the provider could submit updated data." CMS would "require MACs to reopen cost reports for the purpose of revising the Medicaid fraction near the end of the 3-year reopening window and use the Medicaid data at that time to settle the cost report." The first option, thus, would use the reopening process to reduce the PRRB backlog.

The Federation believes that expanded use of the reopening process could turn out to be a reasonable way to reduce the PRRB backlog but, from the provider perspective, the regulatory burden would not be reduced if the appeal backlog is replaced by an equivalent or worse reopening backlog. For this reason, having CMS simply "require MACs to reopen cost reports for the purpose of revising the Medicaid fraction" is, by itself, insufficient. CMS would also need to (a) establish time limits for MACs to issue the Notice of Reopening (perhaps 30 days) and RNPR (we recommend 180 days from the date of the reopening letter), (b) provide sufficient funding so that MACs can complete these tasks in a timely manner, and (c) audit MACs regularly to make sure they meet these timeframes. For PRRB appeals, providers have some ability to move the process along by, for example, asking the PRRB (a third party decision-maker) to schedule a hearing. That option would not be available where an issue is remanded to, or reopened by, a MAC, where it could sit for several years without any action. Hence the need for strict timeframes. Also, where MACs do not meet these timeframes, regulations should give the providers the ability to appeal to the PRRB.

CMS would require MACs to reopen "near the end of the 3-year reopening window and use the Medicaid data at that time to settle the cost report." It appears that CMS believes that waiting until the end of the 3-year reopening period will allow as much time as possible for States to update their Medicaid-eligibility files. But providers should be able to request that the reopening take place sooner. The Federation thus asks that CMS make 3 years the outside limit, while allowing providers to request to have the reopening completed sooner. We also do not believe that it is appropriate to limit the number of reopenings that a provider could seek, particularly because hospitals sometimes seek reopenings to reduce their Medicaid-eligible days where, for example, the State incorrectly had identified an individual as eligible who was not.

The Federation also notes that providers sometimes request additional Medicaid-eligible "timing" days as one step in their efforts to qualify for DSH. Thus, the provider still might not qualify even after the days are added. Under these circumstances, the financial impact of the reopening might be below the MAC's dollar threshold for granting a reopening. The Federation asks CMS to require reopening on this issue without regard to the immediate financial effect.

Also, to make the first proposal more workable, consistent with the sixth "action initiative" in Section XI of the preamble to the Proposed Rule (84 Fed. Reg. at 19579), we believe that the PRRB should modify PRRB Rules 46 and 47.2.3 to state that (a) these Rules apply whenever (not just "simultaneous to the appeal filing") a provider withdraws an issue (not

all issues) from a PRRB appeal to try to resolve it through reopening and (b) the PRRB will automatically reinstate an appeal (or issue) where the MAC does not timely reopen a cost report, without regard to whether the appeal is "jurisdictionally and procedurally valid" or any objection to reinstatement from the MAC.

As an aside, we note that PRRB Rule 46 also sets forth the process for providers to use to withdraw an issue that the MAC has agreed to reopen in writing. However, some MACs refuse to issue a notice of reopening for an issue until after the issue has been withdrawn, which inhibits the potential use of Rule 46 to reduce the PRRB's case load. The Federation asks CMS to clarify that MACs should issue notices of reopening without first requiring providers to withdraw the affected issue from the PRRB appeal in which it is pending.

Upon reinstatement, the MAC and the Board would be able to take any actions regarding jurisdictional and procedural validity that they could have taken before the case was withdrawn. This change would prohibit the PRRB from refusing to reinstate an appeal because of a potential MAC jurisdictional (or other) challenge. Rather, the MAC's challenge would be addressed before the PRRB, exactly as it would have been if the provider had not withdrawn the appeal to pursue reopening,

The second proposal is a "one-time option" to allow hospitals "to resubmit a cost report with updated Medicaid eligibility information, somewhat similar to our existing DSH policy allowing hospitals a one-time option to have their SSI ratios calculated based on their cost reporting period rather than the Federal fiscal year." The Federation is unclear how this "one-time option" is different from (and superior to) seeking reopening, as discussed above, given that it appears to arise after the cost report has been audited and the NPR issued. Also, hospitals already have the opportunity to submit an amended cost report with additional Medicaid-eligible timing days within a year after initial filing and that process is working well.

If the purpose of this proposal is to give hospitals the explicit right to submit an amended cost report with additional Medicaid-eligible timing days more than a year after initial submission, the Federation is supportive, provided that the timing and other issues discussed above are taken into account. But the Federation disagrees that this should be a "one-time" opportunity because hospitals may have more than one update. Moreover, we note that, even though MACs will accept an amended cost report within a year after initial submission, they will not accept any additional information after they start the desk review. We believe that efficiencies could be achieved if MACs would accept data up until (and even during) the audit because it could reduce the number of submissions providers might need to make.

The Federation and its hospitals look forward to working with CMS to improve the process of claiming DSH Medicaid-eligible days, to improve the settlement process, and to reduce the PRRB backlog. In doing so, we suggest that any new rules regarding the PRRB appeals process should be implemented only on a prospective basis.

OUTLIER PAYMENTS

Addendum II.A.4.h. Proposed Outlier Payments

For FY 2020, CMS has proposed that a case be eligible for high cost outlier payments when the cost of the case exceeds the sum of the of the prospective payment rate for the diagnosis related group ("DRG"), any indirect medical education ("IME") and disproportionate share hospital ("DSH") and Uncompensated Care payments, any add-on payments for new

technology and the proposed fixed loss threshold of $26,994. The present threshold, which has been in effect since October 1, 2018, is $25,769. This greater than $1200 increase is on top of an increase of more than $2000 in the threshold between FYs 2017 and 2019. CMS indicates that it has used the same methodology to calculate the fixed loss threshold as it has since FY 2014 with two exceptions (we address below (a) how the agency proposes to address new treatments such as CAR-T with regard to outlier payments and (b) incorporating the impact of outlier reconciliation in the threshold determination). Just as with last year's rulemaking, we are concerned with the lack of transparency associated with the agency's assessment of the charge inflation component of the fixed loss threshold calculation, as we explain below.

The proposed threshold for FY 2020 represents an increase of more than $2200 over the outlier threshold CMS used for FY 2017, with no clear basis in the data made available to commenters to explain why such a dramatic increase in the threshold would be required to approximate the 5.1% target for outlier payments (5.13% taking into account CMS's proposed methodology to incorporate outlier reconciliation) as a portion of total DRG payments. We are particularly concerned about the magnitude of the increase given that for FY 2018, when the threshold was set at $26,537, the Watson Policy Analysis ("WPA") at p.5 indicates that outlier payments as a proportion of DRG payments will be a low 4.89% as compared to the target threshold.[22] First quarter data for FY 2019 indicates a calculated outlier portion of 4.58% to DRG payments.[23] Given that the thresholds applied in FYs 2016 through 2019 appear to result in total outlier payments lower than the 5.1% target, it is particularly questionable whether such a significant increase in the threshold is warranted.

CMS's Decision to Use Charge Inflation Data from Federal Fiscal Years Rather Than Calendar Years Can Add Transparency to the Process.

Telling for the FAH and problematic for purposes of our comments the last several years, we noted that though CMS provided a new table with quarterly total charges and claims data for the eight quarters that CMS used to calculate the charge inflation factor, the data was only provided in totals and the source of the data was not identified. In particular, the figures in the table could not be matched with publicly available data sources, and since CMS did not provide any guidance that described whether and how it edited the data to arrive at the total of quarterly charges and charges per case, the table was not useful in assessing the accuracy of the charge inflation figure. In the FY 2020 proposed rule, 86 Fed. Reg at 19596, CMS announces its decision to rely on charge data from FYs 2017 and 2018. We believe the decision to move to this publicly available data was a thoughtful choice for the proposed rule. We do not believe that such less current data should be used for the final rule. Rather, CMS should disclose all aspects

[22] See the attached WPA report *Summary of Research Modeling FY 2020 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment 2). All of the tables contained in this comment are set forth in and derived from the WPA Report.

[23] WPA Report at p.9. Although the FAH continues to support factoring outlier reconciliation into the threshold calculation, we believe CMS is conflicted on the FY 2019 data. On the one hand, when discussing the establishment of the proposed outlier threshold, CMS indicates it has no FY 2019 data to evaluate their estimate of the threshold. 86 Fed. Reg. at 19599. However, *id*. at 19638, CMS states: "This estimated increase also reflects an estimated increase in outlier payments of 0.5 percent … from our current estimate of FY 2019 outlier payments of approximately 4.6 percent…." That 4.6% estimate for FFY 2019 is entirely consistent with the referenced WPA calculation of 4.58%. CMS needs to ensure that staff preparing estimates for outlier share such estimates with the staff responsible for setting the outlier threshold. This estimate is critical information that suggests there should be no increase in the threshold for FY 2020.

of its edits to the most current data used for the proposed rule and commit to the same process and methods when it recalculates the threshold for purposes of the final rule. Additionally, CMS should commit to make the data files it uses for the final rule, including all edits and calculations, when it publishes the final rule.

Accounting for Outlier Reconciliation

The FAH has repeatedly requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold. In this year's proposed rule, 86 Fed. Reg at 19592, CMS has addressed our prior comments and proposes to incorporate a process to account for outlier reconciliation in this year's outlier threshold calculation. We commend CMS for taking these steps. We have two requests regarding the process CMS proposes to use to calculate the impact of reconciliation on the establishing the outlier threshold. First CMS proposes to use FY 2014 HCRIS data to calculate the total reconciliation that will impact its threshold calculation. CMS expressed that FY 2014 is the first complete year from an available data perspective. We reviewed the HCRIS files for FYs 2012 through 2014 for completeness. During the course of that review we discovered, for example, that in the FY 2013 HCRIS file, 8 of the 17 cost reports indicated a 2013 reconciliation amount that was updated in 2019. There were no changes in HCRIS to the FY 2012 cost reports during the last year. We are concerned that the FY 2014 reconciliations are still subject to change and suggest CMS use FY 2012 data for purposes of this year's outlier threshold calculation.

Second, we request that CMS confirm and document that it took the following steps in calculating the reconciliation amount to be included in its threshold calculation:

1) Exclude Maryland hospitals from the analysis,
2) Base the list of IPPS providers on all Medicare participating providers in FY 2014 and do not restrict consideration to only current IPPS providers,
3) If a provider has multiple cost reports, use all of them, and
4) If there were multiple columns for the line in the cost report, only the first column should be used.

We also request CMS describe any other steps they took in the analysis.

Accounting for CAR-T Cases and Hi-Tech Payments in the Outlier Threshold Calculation

We have significant concerns with whether and how CMS is accounting for high-cost CAR-T cases, and new technology payments associated with those cases that began in FY 2019, in calculating the outlier threshold.[24] We have reviewed the data for the MS-DRG associated with CAR-T. When CMS set the weight for this MS-DRG for this year, it excluded 35 cases from 159 total CAR-T cases for this code because the charges on those cases exceeded the threshold for being trimmed from the DRG weight calculation. However, the data suggests that the charges for those cases legitimately reflected the very high costs of patients needing this treatment. These cases exceeded CMS's trim thresholds by being averaged with much lower cost cases that do not include the CAR-T treatment and other clinical trial cases where the

[24] We express these same concerns with all MS-DRGs that have a component of new technology payments and all very high charge cases where charges represent the provision of actual services, but that are trimmed from the calculation of MS-DRG weights. The discussion below of CAR-T, and later of very high charge cases, are an example of these general concerns.

hospital does not have a cost for the CAR-T product. The resulting weight from this exclusion was 6.5929. Had those 35 cases been included in the weight calculation, the resulting weight would have been 7.1275. Excluding these 35 cases from the weight calculation resulted in significantly reduced reimbursement for this MS-DSG. That reduced reimbursement results in an increased outlier reimbursement for these MS-DRGs. A number of these cases were clinical trials, and in many clinical trial cases, the provider may report only a nominal $1 charge on their Medicare claims for the drug products and other items and services that are provided without cost or paid for by the clinical trial sponsor.

These cases either should be dropped from the calculation of the weight, or the average sales price should be added to these cases to calculate the weight. In either instance, the weight would increase, base reimbursement for the MS-DRG would increase, and the outlier payments would decrease. We request CMS revisit the relative weight calculation to include cases with legitimately high charges as well as excluding or appropriately valuing clinical trial cases where the hospital has no costs for the CAR-T product. We have attached an Excel spreadsheet from WPA with these considerations as Attachment 3 hereto.

Finally, we cannot confirm from the data CMS provided for the proposed outlier threshold whether CMS modeled and included the significant new technology payments that would apply in 2019 and in 2020, when it included claims for the MS-DRG that would include CAR-T payments. If the claims used in the calculation predated FY 2019, and they do in fact relate to FY 2018, they would not have included such payments and that would otherwise significantly reduce or eliminate outlier payments for these cases. As a general matter, new technology add-on payments should be modeled and included for claims that pre-date the first fiscal year in which the payments are available.

Taking the factors noted above into account just for these 35 CAR-T cases would have reduced the threshold by slightly less than $100 this year. Incorporating these considerations in the threshold calculation methodology is increasingly important because it is expected that the use of CAR-T and potentially other similarly expensive drugs will increase significantly over the next few years and those cases must be reimbursed fairly at the base and new technology payment levels, or they could swamp the outlier payment system.

Extreme Charge Cases Significantly Skew the Fixed Loss Threshold

The FAH also asks CMS to consider whether it is appropriate to include extreme cases when calculating the threshold and whether recent volume increase in such cases points to a larger problem that CMS should investigate. WPA conducted various examinations and probing of data to understand the factors that drove CMS to increase the threshold over $4,000 between FY 2017 and FY 2019 and observed that the inclusion of extreme cases in the calculation of the threshold significantly impacts its determination.

In the IPPS rate-setting process for the DRG relative weights, statistical outliers (i.e., extreme cases) are generally removed from calculations on the basis that they improperly skew those calculations. In calculating the outlier threshold, however, those statistical outliers are not excluded from the calculation. To observe the impact of these statistical outliers on the calculation of the threshold, WPA calculated how the threshold would differ after the removal of cases that had total charges above particular trim points. The results of WPA's analysis are included in the tables below for FYs 2019 and 2018:

FY 2020 Proposed Rule Table

Trim threshold	Number of cases removed	Calculated FLT	Percentage of cases trim removes
None	-	$27,022	0.00%
$2,000,000	1,152	$25,248	0.01%
$1,750,000	1,666	$24,895	0.02%
$1,500,000	2,606	$24,370	0.03%
$1,250,000	4,418	$23,601	0.05%
$1,000,000	8,019	$22,528	0.10%
$750,000	17,432	$20,747	0.21%
$500,000	50,541	$17,531	0.60%

The FY 2020 table illustrates that the removal of a relatively small number of extremely high cost (using total charges as a proxy for cost) cases from the calculation significantly decreases the threshold. For example, removing all cases with total charges above $2,000,000 (1152 cases) drives the threshold down over $1,700. Removing all cases at certain other thresholds, lower than $2,000,000, but still high enough to be considered extreme high cost cases, drives the threshold down even further. For example, removing all cases with total charges above $1,000,000 (8019 cases) drives the threshold down almost $4,500, and removing all cases with charges above $500,000 (50,541 cases) drives the threshold down over $9,500. A comparison of the two tables indicates these cases are increasing quickly over time, but still represent a very small percentage of total cases.

To demonstrate this trend of an increase in extremely high charge cases, WPA created the following table illustrating the number of cases with covered charges above $1.5 million for each of the past several years:

Year	Number of cases over $1.5 million	Percentage of total cases	Number of unique providers
2011	926	0.0088%	272
2012	994	0.0098%	272
2013	1,092	0.0111%	283
2014	1,329	0.0141%	306
2015	1,539	0.0161%	320
2016	1,733	0.0185%	334
2017	2,291	0.0250%	403
2018	2,606	0.0309%	393

Within the 2,606 cases with covered charges more than $1.5 million in FY2018:

1) The three most common DRGs responsible for nearly 60% of the cases were:
   a) 003 - ECMO OR TRACH W MV >96 HRS OR PDX EXC FACE, MOUTH & NECK W MAJ O.R. (37.84% of the cases),
   b) 001 - HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM W MCC. (14.81% of the cases), and
   c) 004 - TRACH W MV >96 HRS OR PDX EXC FACE, MOUTH & NECK W/O MAJ O.R. (6.49% of the cases); and

2) The distribution of these high charge cases is less concentrated at the provider level:
   a) The provider with the greatest number of high charge cases had 8.40% of the cases,
   b) The provider with the second greatest number of high charge cases has 6.22% of the cases, and
   c) All other providers had less than 4% of the cases.

If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the impact of this population of cases on the threshold will likewise increase. Thus, it is imperative that CMS carefully consider what is causing this trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, or whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs. A 2013 OIG Report, Medicare Hospital Outlier Payments Warrant Increased Scrutiny, https://oig.hhs.gov/oei/reports/oei-06-10-00520.asp., concurs with this view.

The FAH urges CMS to carefully study this problem as it pertains to outlier payment policy. Not only is this consistent with the calculation process used for IPPS rate setting generally, but it will also produce a threshold that more accurately reflects the universe of cases.

Calculation of Actual Outlier Payment Percentages Based on Actual Historical Payment Data

The FAH believes it is absolutely critical to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1% target. It is impossible for CMS to appropriately modify its methodology to achieve an accurate result if it is not aware of, or is misinformed about, the magnitude of inaccuracies resulting from prior year methodology. We are pleased that CMS's estimate of 4.94% of outlier payments as a percentage of DRG payments for FY 2018 is very close to WPA's actual estimate (WPA Report at 5) using the most recently updated MedPAR file:

Data Source	Operating IPPS Payments Net of IME, DSH and Outlier Amounts ($) (Does not include Capital	Outlier Payments ($)	Outlier Payment Level (%)	Total Medicare Payment ($)
MedPAR 2018 Actual Outlier Payments, FY 2018 Final Rule Impact File Adjustment Factors. Correction Notice version	$93,473,251,511	$4,570,696,570	4.89%	$ 114,407,738,574

As demonstrated by the following table from WPA Report at p. 6, the use of more recent HCRIS data (i.e., the March file versus the December file) also has a significant impact on the calculation of the actual outlier payment level:

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	$75,513,803,937	$3,820,292,807	4.82%	$4,058,170,707	($237,877,900)
FY 2013 (March)	3,047	$80,760,714,604	$4,270,125,578	5.02%	$4,340,143,777	($70,018,199)
FY 2014 (December)	2,388	$63,505,784,324	$3,085,415,408	4.63%	$3,412,850,369	($327,434,961)
FY 2014 (March)	3,054	$82,479,662,313	$4,343,131,876	5.00%	$4,432,521,368	($89,389,492)
FY 2015 (December)	2,850	$78,849,610,927	$3,847,264,205	4.65%	$4,238,185,938	($390,921,733)
FY 2015 (March)	3,036	$84,552,076,553	$4,283,484,754	4.82%	$4,543,853,974	($260,369,220)
FY 2016 (December)	2,852	$81,185,256,122	$4,223,366,030	4.94%	$4,362,921,000	($139,554,970)
FY 2016 (March)	3,048	$87,553,087,944	$4,689,098,313	5.08%	$4,705,190,000	($16,091,687)
FY 2017 (December)	2,989	$79,429,360,478	$3,912,972,441	4.70%	$4,268,623,000	($355,650,559)
FY 2017 (March)	3,244	$88,346,767,109	$4,686,222,555	5.04%	$4,747,820,000	($61,597,445)
FY 2018 (March)	594	$15,857,684,910	$683,919,363	4.13%	$852,200,000	($168,280,637)

Note: 2018 data does not have all providers' cost report yet.

FAH emphasizes the importance of CMS using the most recent data available to more accurately assess the outlier payment level. The trend from this data indicates CMS has fallen short of its 5.1% outlier target since at least 2013, and yet it is still proposing a significant increase in the threshold this year with no rationale offered by CMS to explain the prior year shortfalls in payment.

Using Most Recent Data to Calculate the Threshold

We also note that with each rulemaking, until FY 2017, the final outlier threshold established by CMS was always significantly lower than the threshold set forth in the proposed rule. The table below from WPA Report at p.7 expresses this trend graphically.

FY	Proposed	Final	Variance	% of Variance
2009	$ 21,025	$ 20,045	$ (980)	-4.66%
2010	$ 24,240	$ 23,140	$ (1,100)	-4.54%
2011	$ 24,165	$ 23,075	$ (1,090)	-4.51%
2012	$ 23,375	$ 22,385	$ (990)	-4.24%
2013	$ 23,630	$ 21,821	$ (1,809)	-7.66%
2014	$ 24,140	$ 21,748	$ (2,392)	-9.90%
2015	$ 25,799	$ 24,626	$ (1,173)	-4.55%
2016	$ 24,485	$ 22,544	$ (1,941)	-7.93%
2017	$ 23,681	$ 23,573	$ (108)	-0.46%
2018	$ 26,713	$ 26,537	$ (176)	-0.66%
2019	$ 27,545	$ 25,769	$ (1,776)	-6.45%
2020	$ 26,994			

While the FAH can only speculate as to why this drop in the threshold occurs, the FAH believes the decline is most likely due to the use of updated CCRs and/or additional/other data in calculating the final threshold. This again emphasizes that CMS must use the most recent data in order to appropriately calculate the outlier threshold. Please see our discussion above concerning our view that less current but publicly available data can serve a limited role in the proposed rule process.

With regard to the current rulemaking, WPA was able to replicate the threshold within $28, accepting CMS's charge inflation factor as accurate only because it could not replicate that factor due to a lack of supporting information for CMS's calculation. Thus, we have high confidence that WPA understands CMS's methodology and has accurately modeled that methodology such that inputting more current data will yield a threshold that will be more likely to meet the target percentage of 5.1%.

The FAH is not proposing a threshold for FY 2020. While we have confidence in the work of WPA, its work is dependent on large variables in the outlier calculation. We also note that the impact of the inclusion of extreme cases in the calculation of the fixed loss threshold is significant and we urge CMS to carefully study this trend and whether outlier payment policy needs to be adjusted so that it is fair to all hospitals that fund outlier payments. Finally, we recognize that with the release of the MedPAR Final data with additional claims, which will lead to new weights being calculated, including consideration of our suggestions on CAR-T payment data, and with updated cost to charge ratios, it is appropriate to recalculate the fixed loss threshold from the data that will be released with the final rule.

* * * * *

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President Policy, at sspeil@fah.org or 202-624-1529.

Sincerely,

ATTACHMENT 1

WATSON POLICY ANALYSIS

Computed weights for different CAR-T scenarios
DRAFT -- Subject to revision
Date: June 6, 2019, revised on 6/11 to fix an issue on the FLT.
Based on FY2020 IPPS replication using FY2018 data

Scenario	DRG	Source	Weight	Cases
Replication	016	CMS	6.7587	2,332
	016	WPA	6.5929	2,321
Adjust trim not removing statistical outliers	016	WPA	7.1275	2,356
New DRG	New	WPA	16.5385	159
	016	WPA	6.4394	2,196
New DRG, no drugs	New	WPA	4.5211	159
	016	WPA	6.4401	2,196
New DRG, Drugs at a CCR of 1.0 in new DRG	New	WPA	67.4086	159
	016	WPA	6.4362	2,196
New DRG, Drugs at a CCR of 0.5 in new DRG	New	WPA	35.9744	159
	016	WPA	6.4382	2,196

Illustrative examples of scenarios
Note: This is to just highlight a few illustrative examples of some of the interactions
Repeat: **Illustrative** and slightly simplified, especially on the new tech, since not assuming a cost on the new tech.

Effective base payment amount (assumptions on IME/DSH)	$ 10,000
Cost of a CAR-T case including drugs	$ 500,000
New Tech percentage	65%
Outlier FLT	$ 27,000
Outlier percentage	80%

	Scenario 1: Base, replication, no new tech	Scenario 2: Base, replication, yes new tech	Scenario 3: New DRG, no new Tech	Scenario 4: New DRG, no new Tech	Scenario 5: New DRG, no drugs (taking drug cost out)
Cost of case	$ 500,000	$ 500,000	$ 500,000	$ 500,000	$ 127,000
DRG Weight	6.5929	6.5929	16.5385	16.5385	4.5211
Base payment	$ 65,929	$ 65,929	$ 165,385	$ 165,385	$ 45,211
Difference between cost and payment	$ (434,071)	$ (434,071)	$ (334,615)	$ (334,615)	$ (81,789)
New Tech (Y/N)	N	Y	N	Y	N
New Tech amount	$ -	$ 282,146	$ -	$ 217,500	$ -
Difference after accounting for New Tech	$ (434,071)	$ (151,925)	$ (334,615)	$ (117,115)	$ (81,789)
Fixed Loss Threshold amount	$ 27,000	$ 27,000	$ 27,000	$ 27,000	$ 27,000
Difference after accounting for FLT	$ (407,071)	$ (124,925)	$ (307,615)	$ (90,115)	$ (54,789)
High Cost Outlier payment:	$ 325,657	$ 99,940	$ 246,092	$ 72,092	$ 43,831
Total payment for case	$ 391,586	$ 448,015	$ 411,477	$ 454,977	$ 89,042
Profit/Loss after also accounting for High Cost Outlier:	$ (108,414)	$ (51,985)	$ (88,523)	$ (45,023)	$ (37,958)

No drug payment

ATTACHMENT 2

Summary of research modeling

FY 2020 Proposed Inpatient Prospective Payment System

Outlier Payments

Date: June 17, 2019

Introduction

Watson Policy Analysis (WPA) was asked to analyze issues and replicate outlier payments from the Centers for Medicare & Medicaid Services (CMS) Fiscal Year (FY) 2020 Inpatient Prospective Payment System (IPPS) proposed rule. In short, this outlier policy sets forth a set of rules whereby CMS provides payment to inpatient hospitals for a portion of their high cost inpatient cases once particular thresholds are met. CMS describes its methodology and logic starting on page 19591 of the Federal Register.[1] We attempted to replicate the CMS logic and then compared our results and made a variety of adjustments to assess the impact of using different parameters. This report summarizes our findings.

Summary

A summary of findings is as follows:

- WPA was able to come close to the CMS calculation of the Fixed Loss Threshold (FLT). CMS published $26,994. Using the weights reported by CMS, WPA calculated $27,022.
- WPA replicated other factors that went into the payment calculation.
- WPA was able to replicate the CMS calculation of the necessary adjustment for the target percentage based on the outlier reconciliations reported in the cost reports.
- WPA calculated an actual outlier payment proportion of 4.89% versus the 4.94% reported in the rule for FY 2018. As a part of the rate-setting, the target percentage is intended to be 5.1%
- WPA was able to come close to the estimate of charge inflation. CMS reported a charge inflation of 5.446% while WPA has calculated 5.376%.

Background on outlier payments

In the IPPS program, CMS has established the concept of “outliers” to be high cost cases which are paid an additional amount so that providers’ potential losses are limited. When the estimated costs of a case exceed the payment for the case, plus a threshold, CMS will generally pay 80% of the costs that exceed the payment plus the threshold. CMS pays 90% for discharges assigned to one of the “burn” diagnosis related groups (DRGs).

[1] "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals”. *Federal Register* Vol. 84, No. 86, Friday, May 3, 2019

This threshold is known as the "fixed loss threshold" (FLT) and is set prospectively with each rule based on a target that operating outlier payments will be 5.1% of total operating payments, including outliers. This target is determined by simulations of expected payments.

Background from CMS on outlier payments can be found at:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html

Additional detail is provided by CMS each year in the IPPS rule.

Analysis 1: Replication of the CMS estimated FY 2020 outlier payment from the FY 2020 IPPS proposed rule

WPA estimated payments, including outlier payments from the FY 2020 Proposed Medicare Provider Analysis and Review (MedPAR) Proposed File, following the methodology set forth in various IPPS rules. In modeling payments, WPA used information from the following data sources:

- MedPAR FY 2020 proposed file: contains inpatient hospital claims from FY 2018 that were used by CMS to model proposed FY 2020 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2020,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2020 Proposed IPPS rule, in particular information on cost and charge inflation factors, and
- Inpatient Provider of Services File: contains provider specific information.
- Hospital Cost Reporting Information System (HCRIS) data containing cost reports from providers. This information was used to calculate the adjustment to the outlier target based on the historical outlier reconciliation.

In addition, other factors such as charge inflation, CCR adjustment factors, and standardized payment amounts from the proposed rule were used.

Complete payments were calculated including operating, capital, disproportionate share hospital (DSH), indirect medical education (IME), uncompensated care, etc. for each case, following the CMS methodology. The CMS methodology excludes sole community hospitals, hospitals that have become Critical Access Hospitals (CAHs), and Maryland hospitals.

WPA calculated a fixed loss threshold of: $27,022 versus the published number of $26,994, a difference of $28 or about 0.10%.

Although there are not many CAR-T cases, they do have an impact on the Fixed Loss Threshold. If the CAR-T cases are included as currently reported in the data with no New Technology Payment, the Fixed Loss Threshold is estimated to be $26,929. In reality, at least some of the CAR-T cases should be receiving a New Tech payment, so that had been known, the true value of the FLT is expected to between this value and what was modeled for the replication.

Please note that the FLT will adjust with the release of the final rule and associated files, in addition to the recalculated weights

Analysis 2: Comparison of Cost-to-Charge ratios from the FY 2020 proposed rule Impact file and the Inpatient Provider Specific File

As part of the analysis, we compared the CCRs included in the impact file (used in modeling the FLT) with the CCRs from the Provider Specific File (PSF).

Comparing the 3,318 providers listed in the impact file and a simulated December 2018 PSF file, we had a match rate of 97.32% (3,229 providers) for operating CCRs. When comparing the impact file provider list and the March 2019 PSF, we had a match rate of 67.39%.[2]

For the December 2018 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was -0.009% if all providers were used, and -0.5% if just those providers with differences were used.

For the March 2019 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was 0.217% if all providers were used and 0.613% if just those providers with differences were used.

The table of matching statistics reported four years ago in a report from The Moran Company – "Modeling Fiscal Year 2015 Inpatient Prospective Payment System Outlier Payments" dated June 23, 2014, and then updated with WPA calculated data is as follows:

[2] Note: The PSF file for December 2018 was removed before the IPPS rule was released and not downloaded. So as an approximation, we took the March 2019 and restricted it to records in the PSF file prior to 1/1/19, to simulate a December 2018 PSF file. This is consistent with prior years.

IPPS Rule for FY	Matching Rate Between Impact file and Most recent PSF CCRs	Average Percent Difference Between the Impact File and Most Recent PSF Operating CCR of the Same Hospital (weighted By Discharges)
Final 2010*	93.2%	0.4%
Final 2011*	96.4%	0.1%
Final 2012 - Dec 2010 Update	96.9%	0.2%
Final 2012 - March 2011 Update	65.3%	1.6%
Final 2013	92.1%	0.0%
Final 2014	97.2%	-0.1%
Proposed 2015 - Dec 2015 Update	98.8%	-2.7%
Proposed 2015 - March 2015 Update	64.8%	1.0%
Proposed 2016 - Dec 2015 Update	89.6%	-0.02%
Proposed 2016 - March 2015 Update	61.6%	0.19%
Proposed 2017 - Dec 2016 Update	94.16%	-0.014%
Proposed 2017 - March 2017 Update	65.70%	0.236%
Proposed 2018 – December 2017 update	94.33%	-0.017%
Proposed 2018 – March 2018 update	67.33%	-0.342%
Proposed 2019 – December 2018 update	97.33%	-0.002%
Proposed 2019 – March 2019 update	67.69%	0.240%

* Vaida Health Data Consulting, Modeling FY 2013 IPPS Outlier Payment. June 11, 2012

Note that WPA developed new programs to analyze the data, so there may be differences with the previous analyses by The Moran Company and Vaida Health Consulting. However, the matching percentage calculated by WPA is within a similar matching percentage as that calculated by the Moran Company. In addition, the average difference in operating CCR is much smaller.

Analysis 3: FY 2018 Outlier payment using FY 2018 MedPAR data

In order to examine the actual outlier payments, WPA modeled payments and combined outlier payment information to estimate the actual payments. CMS published an estimate that outlier

payments were 4.94%.[3] The chart below shows operating payments and the outlier payments that we calculated. The operating payments and the total payments are based on the modeling simulation. The outlier payment amount is from the reported outlier payments from the MedPAR 2018 Proposed File. In the simulation using the CMS FLT we estimate that outlier payments are 4.89%.

Data Source	Operating IPPS Payments Net of IME, DSH and Outlier Amounts ($) (Does not include Capital	Outlier Payments ($)	Outlier Payment Level (%)	Total Medicare Payment ($)
MedPAR 2018 Actual Outlier Payments, FY 2018 Final Rule Impact File Adjustment Factors. Correction Notice version	$93,473,251,511	$4,570,696,570	4.89%	$ 114,407,738,574

Analysis 4: Outlier payments from Medicare cost reports

For the past several years, WPA has calculated estimated outlier payments based on the HCRIS cost report data. This analysis has been conducted each year as a part of the IPPS proposed rule analysis.

[3] P. 19599 of the Federal Register version of the rule.

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	$75,513,803,937	$3,820,292,807	4.82%	$4,058,170,707	($237,877,900)
FY 2013 (March)	3,047	$80,760,714,604	$4,270,125,578	5.02%	$4,340,143,777	($70,018,199)
FY 2014 (December)	2,388	$63,505,784,324	$3,085,415,408	4.63%	$3,412,850,369	($327,434,961)
FY 2014 (March)	3,054	$82,479,662,313	$4,343,131,876	5.00%	$4,432,521,368	($89,389,492)
FY 2015 (December)	2,850	$78,849,610,927	$3,847,264,205	4.65%	$4,238,185,938	($390,921,733)
FY 2015 (March)	3,036	$84,552,076,553	$4,283,484,754	4.82%	$4,543,853,974	($260,369,220)
FY 2016 (December)	2,852	$81,185,256,122	$4,223,366,030	4.94%	$4,362,921,000	($139,554,970)
FY 2016 (March)	3,048	$87,553,087,944	$4,689,098,313	5.08%	$4,705,190,000	($16,091,687)
FY 2017 (December)	2,989	$79,429,360,478	$3,912,972,441	4.70%	$4,268,623,000	($355,650,559)
FY 2017 (March)	3,244	$88,346,767,109	$4,686,222,555	5.04%	$4,747,820,000	($61,597,445)
FY 2018 (March)	594	$15,857,684,910	$683,919,363	4.13%	$852,200,000	($168,280,637)

Note: 2018 data does not have all providers' cost report yet.

The FY2013 analysis was conducted in the Spring of 2015 during the proposed rule comment period, and each Fiscal year was done in the successive calendar years following that. The month refers to the data release month of the HCRIS data.

Note that these numbers are subject to change as more hospitals submit cost reports and also cost reports are reviewed and revised.

Analysis 5: Fixed Loss Threshold over time

From examining the fixed loss threshold in proposed rules and final rules, there is a pattern of the fixed loss threshold declining. The following table shows the fixed loss thresholds for recent years.

FY	Final	Proposed	Variance	% of Variance
2009	$ 20,045	$ 21,025	$ (980)	-4.66%
2010	$ 23,140	$ 24,240	$ (1,100)	-4.54%
2011	$ 23,075	$ 24,165	$ (1,090)	-4.51%
2012	$ 22,385	$ 23,375	$ (990)	-4.24%
2013	$ 21,821	$ 23,630	$ (1,809)	-7.66%
2014	$ 21,748	$ 24,140	$ (2,392)	-9.90%
2015	$ 24,626	$ 25,799	$ (1,173)	-4.55%
2016	$ 22,544	$ 24,485	$ (1,941)	-7.93%
2017	$ 23,573	$ 23,681	$ (108)	-0.46%
2018	$ 26,537	$ 26,713	$ (176)	-0.66%
2019	$ 25,769	$ 27,545	$ (1,776)	-6.45%
2020		$ 26,994		

Analysis 6: Explorations on high charge cases

As evidenced in Analysis 5, the Fixed Loss Threshold has been adjusting over time, and the FY 2020 Proposed Rule Fixed Loss Threshold is nearly $1,000 higher than the FY 2019 Final Fixed Loss Threshold. In response to this, WPA conducted various examinations and probing of the data and other issues that may relate to the Fixed Loss Threshold.

As noted earlier, the impact of the CAR-T cases is to increase the Fixed Loss Threshold by approximately $90 when New Technology payments are not accounted for. As a result, CAR-T cases are not the cause of the increase in the Fixed Loss Threshold.

No single, definitive, cause for the increase was identified. However, one intriguing finding of this research was:

a) The impact of “extreme” cases on the Fixed Loss Threshold; and
b) The increase in the rate of “extreme” cases.

In the IPPS rate-setting process, statistical outliers – extreme cases – generally are removed from the calculations during the normal methodology. However, these cases are left in during the calculation of the Fixed Loss Threshold.

To examine this issue, WPA tested trimming out cases with covered charges greater than particular thresholds. This removed the case if the ***covered charges*** were greater than a threshold. (Note: For the actual calculation of cost for the Fixed Loss Threshold, covered charges are used. In previous years of this memo, total charges were used. However, covered charges are a more direct representation.)

The following table shows the results at different trim points.

Trim threshold	Number of cases removed	Calculated FLT	Percentage of cases trim removes
None	-	$27,022	0.00%
$2,000,000	1,152	$25,248	0.01%
$1,750,000	1,666	$24,895	0.02%
$1,500,000	2,606	$24,370	0.03%
$1,250,000	4,418	$23,601	0.05%
$1,000,000	8,019	$22,528	0.10%
$750,000	17,432	$20,747	0.21%
$500,000	50,541	$17,531	0.60%

Removing a relatively small number of cases can have the impact of shifting the Fixed Loss Threshold potentially thousands of dollars.

As was noted in previous years, the number and proportion of very high charge cases (defined here as having *covered charges* greater than $1.5 million) have been increasing over time. In the FY2018 data, this trend continued. There is an increase at a much faster rate than previous years for this 2018 data.

Year	Number of cases over $1.5 million	Percentage of total cases	Number of unique providers
2011	926	0.0088%	272
2012	994	0.0098%	272
2013	1,092	0.0111%	283
2014	1,329	0.0141%	306
2015	1,539	0.0161%	320
2016	1,733	0.0185%	334
2017	2,291	0.0250%	403
2018	2,606	0.0309%	393

In terms of the 2,606 cases with covered charges more than $1.5 million in FY2018:

- The three most common DRGs responsible for nearly 60% of the cases were:
  - 003 - ECMO OR TRACH W MV >96 HRS OR PDX EXC FACE, MOUTH & NECK W MAJ O.R. (37.84% of the cases)
  - 001 - HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM W MCC (14.81% of the cases)
  - 004 - TRACH W MV >96 HRS OR PDX EXC FACE, MOUTH & NECK W/O MAJ O.R. (6.49% of the cases)
- The distribution of these high charge cases are less concentrated at the provider level.
  - The provider with the greatest number of high charge cases had 8.40% of the cases.
  - The provider with the second greatest number of high charge cases has 6.22% of the cases.
  - All other providers had less than 4% of the cases.

Analysis 7: Modeling of FY2019 outlier percentage

WPA was asked to examine if it would be possible to provide any estimates of the proportion of outlier payments for FY2019. WPA has made some estimates, but they are subject to significant assumptions. The difficulty is that the FY2019 MedPAR data has not been release released and the year is still ongoing.

However, CMS has started releasing quarterly updates for the Standard Analytic Files (SAF) and the Calendar Year 2018 Q4, which is the same as Fiscal Year 2019 Q1 data has been released.

Using claims from this actual claims data, WPA is currently calculating an outlier percentage of 4.58% for the first quarter of FY2019.

Analysis 8: Outlier Reconciliation

In the FY2020 IPPS rule, CMS is proposing a new methodology to adjust the outlier target percentage to account for outlier reconciliation. WPA was successful in replicating the CMS

calculations exactly given the logic described, after making certain assumptions/decisions about steps not fully documented.

CMS should confirm and have documented the following steps that WPA believes CMS performed:

1) Exclude Maryland hospitals from the analysis
2) Base the list of IPPS providers off of provider in the FY2014 and do not restrict to current IPPS providers
3) If a provider has multiple cost reports, use all of them.
4) If there were multiple columns for the line in the cost report, only the first column should be used.

WPA is not stating an opinion on the appropriateness of the logic as of this time.

Analysis 9: Examination of high charge and outlier cases over time

Analysis 7 of this memo examined high charge cases and their impact on the fixed loss threshold. Analysis 7 was focused on a prospective examination of charges and their impact. This analysis in contrast looks retrospectively at data from each year, generating statistics on high charge cases and the number of outliers, as well as the average outlier amount actually paid in each year.

What can immediately be seen from this analysis is that the number of high charge (measured using covered charges) cases is increasing over time as well as their proportions, and that the average amount in outlier payment per case is increasing over time.

The following tables are based on IPPS cases, note Maryland cases and certain others have not been removed.

		Covered charges				
Year	Count of cases	Over $1.0 million	Over $1.5 million	Over $2.0 million	Number of outlier cases	Total outlier payment
2013	9,834,245	3,908	1,092	430	277,907	$ 4,158,697,607
2014	9,452,816	4,532	1,329	538	291,644	$ 4,543,055,116
2015	9,536,443	5,118	1,539	661	244,640	$ 4,102,515,447
2016	9,418,830	5,822	1,791	764	289,511	$ 4,648,031,627
2017	9,454,488	6,951	2,181	926	288,231	$ 4,847,809,576
2018	9,253,468	8,019	2,606	1,152	241,463	$ 4,579,807,427

In percentage terms and the average outlier amount as computed based on the MedPAR data, the results are as follows:

	Percentage of cases				
Fiscal Year	Over $1.0 million	Over $1.5 million	Over $2.0 million	Number of outlier cases	Average outlier amount
2013	0.040%	0.011%	0.004%	2.826%	$ 14,964
2014	0.048%	0.014%	0.006%	3.085%	$ 15,577
2015	0.054%	0.016%	0.007%	2.565%	$ 16,770
2016	0.062%	0.019%	0.008%	3.074%	$ 16,055
2017	0.074%	0.023%	0.010%	3.049%	$ 16,819
2018	0.087%	0.028%	0.012%	2.609%	$ 18,967

ATTACHMENT 3

WATSON POLICY ANALYSIS

Statistics on high charge cases and outlier payments

Based on MedPAR data from years. Note: ACTUAL for year in what was paid out, NOT modeled for later years

DRAFT -- Note: Quick approximation

May need to be refined (e.g. Maryland hospitals are included)

		Covered charges					Percentage of cases				
Year	Count of cases	Over $1.0 million	Over $1.5 million	Over $2.0 million	Number of outlier cases	Total outlier payment	Over $1.0 million	Over $1.5 million	Over $2.0 million	Number of outlier cases	Average outlier amount
year	_freq_	flag_1m	flag_1halfm	flag_2m	flag_outlier	outlier_amount					
2013	9,834,245	3,908	1,092	430	277,907	$ 4,158,697,607	0.040%	0.011%	0.004%	2.826%	$ 14,964
2014	9,452,816	4,532	1,329	538	291,644	$ 4,543,055,116	0.048%	0.014%	0.006%	3.085%	$ 15,577
2015	9,536,443	5,118	1,539	661	244,640	$ 4,102,515,447	0.054%	0.016%	0.007%	2.565%	$ 16,770
2016	9,418,830	5,822	1,791	764	289,511	$ 4,648,031,627	0.062%	0.019%	0.008%	3.074%	$ 16,055
2017	9,454,488	6,951	2,181	926	288,231	$ 4,847,809,576	0.074%	0.023%	0.010%	3.049%	$ 16,819
2018	9,253,468	8,019	2,606	1,152	241,463	$ 4,579,807,427	0.087%	0.028%	0.012%	2.609%	$ 18,967